

Regulations of Connecticut State Agencies

TITLE 21a. Consumer Protection

Agency

Department of Consumer Protection

Subject

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DESCRIPTION OF ORGANIZATION

Part I

Definitions

Sec. 21a-1-1. Definitions

(a) The term “Commissioner,” as used in these regulations, means the commissioner of consumer protection.

(b) “Department” means the department of consumer protection.

(c) “Division chief” means any departmental employee or employees designated by the commissioner as the head of a particular division of the department.

(d) “License” includes the whole or part of any permit, certification, approval, registration, charter, or similar form of permission required by law to be issued by the department.

(e) “Regulation” means any departmental rule of general applicability that implements, interprets, or prescribes law or policy, or describes the organization, procedure, or practice requirements of the department. The term does not include

(i) rules governing the internal management of the department and not affecting private rights or procedures available to the public, and

(ii) declaratory rulings issued pursuant to section 21a-1-10 of these regulations.

(Effective July 27, 1984)

Part II

Structure and Responsibilities

Sec. 21a-1-2. Creation and authority

The department was established as a separate agency of the state government by public Act 412 of the 1959 General Assembly (Section 21a-1 of the Connecticut General Statutes). The department’s powers are derived from the various statutes which it is charged with administering. These statutes deal generally with food and drugs, pharmacies, weights and measures, and consumer deception.

(Effective July 27, 1984; Amended March 7, 2008)

Sec. 21a-1-3. Commissioner of consumer protection

The commissioner has the overall responsibility for the operation of the department. The deputy commissioner assists the commissioner and is the acting commissioner in his absence. In discharging his responsibilities, the commissioner may delegate certain of his functions to a division of the department, to an individual division chief, to an independent hearing examiner, or to an employee of the department.

(Effective July 27, 1984)

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Sec. 21a-1-4. Official address

The principal office of the department is located at Hartford, Connecticut. All communications should be addressed to the Department of Consumer Protection, State Office Building, 165 Capitol Avenue, Hartford, Connecticut 06106, unless otherwise specifically directed.

(Effective July 27, 1984; Amended March 7, 2008)

Sec. 21a-1-5. General duties and responsibilities

The department is charged with enforcing legislation intended to protect consumers from injury by product use or merchandising deceit. In connection with this responsibility, the department administers a statewide consumer education program designed to alert the public of potentially hazardous products and deceptive trade practices.

(Effective July 27, 1984; Amended March 7, 2008)

Sec. 21a-1-6. Organizational structure and division of responsibilities

The department is composed of the following divisions, the principal duties of which are as follows:

(a) **Administration division.** This division is responsible for all functions relating to budget and fiscal services, payroll and personnel procedures, the ordering of supplies and related support activities.

(b) **Food division — general section.** This division is responsible for safeguarding consumers from injury, filth, and deception pertaining to the manufacture, storage and sale of foods in intrastate commerce. The laws administered by this division include the Pure Food and Drug statutes, the Unit Pricing Act, and certain provisions of the Uniform Food, Drug, and Cosmetic Act.

(c) **Drug, device and cosmetic division.** This division is responsible for insuring that drug products, medical devices, cosmetic products, and children's toys are accurately labeled and suitable for the purposes intended. The laws administered by this division include the Child Protection Act, the Dependency-Producing Drug statutes, and certain provisions of the Uniform Food, Drug and Cosmetics Act.

(d) **Weights and measures division.** This division is responsible for safeguarding the public in all matters involving commercial determinations of quantity. The provisions contained in Title 43 of the General Statutes are administered by this division.

(e) **Consumer frauds division.** This division processes and investigates consumer complaints regarding deceptive trade practices and untrue or misleading advertisements. It also licenses or otherwise regulates itinerant vendors, going out of business sales, and the sale of cigarettes. The Unfair Sales Practices Act and the Uniform Deceptive Trade Practices Act are administered by this division.

(f) **Consumer education division.** This division is responsible for keeping the public abreast of the activities of the department and informing consumers of potentially hazardous products and deceptive trade practices. All written information is disseminated in both the

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English and Spanish languages, whenever practicable.

(Effective July 27, 1984; Amended March 7, 2008)

RULES OF PRACTICE

Part III

Dealings with the General Public

Sec. 21a-1-7. Departmental policy on public information

(a) The policy of the department is to make available for public inspection all files, records, documents and other materials within its possession, unless prohibited by law. A compilation of all regulations, policy statements, final orders, decisions, and official opinions is available for public inspection at the office of the commissioner.

(b) Departmental employees are not permitted to release information about a particular individual or firm unless a complaint has been issued or an order has been secured against such individual or firm. Information may be released concerning

(i) the allegations contained in a complaint issued pursuant to Section 21a-1-21 of these regulations;

(ii) a final decision or order secured by the department in a contested case;

(iii) the contents of a complaint issued by a consumer affairs agency in another state or by the Federal Trade Commission; and

(iv) an order secured against a particular individual or firm by any state or federal court, by a consumer affairs agency in another state, by the Federal Trade Commission, or by any other federal agency.

(Effective July 27, 1984)

Personal Data Systems

Sec. 21a-1-7a(a). Authority

These regulations are promulgated pursuant to the provisions of section 4-196 of the General Statutes.

(Effective May 15, 1984)

Sec. 21a-1-7a(b). Definitions

(a) The terms set forth in section 4-190 of the General Statutes, as amended, shall have the same meanings in this regulation as therein defined.

(b) "Department" means the Department of Consumer Protection, 165 Capitol Avenue, Hartford, Connecticut 06106, and includes all boards and commissions within said department as defined by section 21a-6 of the General Statutes.

(Effective May 15, 1984; Amended March 7, 2008)

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Sec. 21a-1-7a(c). Categories

(a) **Licensee files.** The licensee personal data system consists of financial, employment, criminal history and other personal background data and information secured and maintained by the department for individuals licensed by the department.

(b) **Complaint files.** The complaint file personal data system consists of correspondence files relating to complaints or inquiries received by the department concerning the conduct or method of doing business of individuals, companies or other organizations regulated or licensed by the department. Active complaint files are maintained separately from the file containing the licensee licensure data; closed out or resolved complaint files are subsequently consolidated, as appropriate, into the licensee personal data system.

(c) **Personnel files.** The personnel files personal data system consists of payroll and personnel data. Said data consists of payroll data, personnel status, attendance records, addresses, telephone numbers, educational data, financial data, medical data and employment data.

(d) **Agency financial files.** The agency financial file personal data system consists of payments to vendors, travel records of agency employees, expense statements of agency employees, mileage reports of agency employees and all other routine financial data.

(Effective May 15, 1984)

Sec. 21a-1-7a(d). Nature and purpose of personal data systems

(a) The nature and purpose of the licensee personal data system is to maintain an accurate and current information base upon which to determine and ascertain that all licensees licensed or to be licensed by the department are qualified, fit and suitable to be licensed for the particular activity authorized by the department.

(b) The nature and purpose of the complaint file personal data system is to receive, maintain, investigate and act upon complaints concerning the conduct or method of doing business of all persons regulated by the department.

(c) The nature and purpose of the personnel file personal data system is to maintain an accurate and current information base needed to fulfill the department's responsibility in the proper administration of said department. Said information is used to substantiate payrolls; to substantiate leave balances and/or retirement; to substantiate health/life/disability insurance, social security and retirement benefits; to substantiate affirmative action policies; and other areas as directed by state statutes and regulations.

(d) The nature and purpose of the agency financial file personal data system is to maintain an accurate and current information base needed to fulfill the department's responsibility in the proper fiscal administration of the department.

(Effective May 15, 1984)

Sec. 21a-1-7a(e). Procedures regarding the maintenance of personal data

(a) All employees who function as custodians of the department's personal data systems or who have access thereto shall be given a copy of the provisions of Chapters 3 and 55 of

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the General Statutes together with a copy of these regulations.

(b) All such departmental employees shall take reasonable precautions to protect personal data under their supervision from the danger of fire, theft, flood, natural disaster and other physical threats.

(c) Except for departmental employees a record shall be maintained of each person, individual, agency or organization who has obtained access to or to whom disclosure has been made of personal data, pursuant to Chapter fifty-five of the Connecticut General Statutes, together with a reason for each disclosure or access. Upon written request this record shall be made available to the individual who is the subject of the personal data disclosure.

(d) The department shall maintain only such personal data as is relevant and necessary in order to accomplish the statutory authorization to maintain such information.

(e) Upon receipt of a written request, the department shall, within four business days thereafter, mail or deliver to individuals a written response to the question of whether the department maintains personal data concerning such individual.

(f) Except where precluded by law, the department shall disclose to any person upon request, all personal data, concerning him which is maintained by the department. Such disclosure shall be conducted so as not to disclose any personal data concerning persons other than the individual requesting such information.

(g) If the department refuses to disclose personal medical data to a person and the non-disclosure is not mandated by law, the department shall, at the written request of such person, permit a qualified medical doctor to review the personal medical data contained in the person's record to determine if the personal medical data should be disclosed. If disclosure is recommended by the person's medical doctor, the department shall disclose the personal medical data to such person; if non-disclosure is recommended by such person's medical doctor, the department shall not disclose the personal medical data and shall inform such person of the judicial relief provided under section 4-195 of the General Statutes.

(Effective May 15, 1984)

Sec. 21a-1-7a(f). Procedures for contesting content

The following procedure shall be used in order to provide an opportunity to contest the accuracy, completeness or relevancy of personal data:

(a) Any individual may file a request with this department for correction of personal data pertaining to him.

(b) Within thirty days of receipt of such request, the department shall notify such individual that it will make the correction or, if the correction is not to be made as submitted, shall state the reason for its denial of such request.

(c) Following such denial by the department, the individual requesting such correction shall be permitted to add a statement to his personal data record setting forth what he believes to be an accurate or complete version of the personal data in question. Such statements shall become a permanent part of the department's personal data system and

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shall be disclosed to any individual, agency or organization to which the disputed personal data is disclosed.

(Effective May 15, 1984)

Dealings with the General Public

Sec. 21a-1-8. Departmental proceedings open to the public

(a) All rule-making and licensing proceedings shall be open to the public. Prior to any proceedings to adopt or promulgate new rules and regulations, a public hearing will be held and the time and place of such hearing will be duly publicized. A special effort will be made to contact any person or firm whose rights or duties would be most directly affected by the proposed regulations.

(b) All investigational proceedings prior to the issuance of a formal complaint by the department are not open to the public. The contents of investigational files and inspection reports shall remain confidential unless made a part of the record in an adjudicative proceeding or unless provided otherwise by statute.

(c) The issuance of a complaint by the department, as provided in section 21a-1-21 of these regulations, is a matter of public record. All adjudicative proceedings after the issuance of a complaint are open to the public.

(Effective July 27, 1984)

Sec. 21a-1-9. Consumer complaints and requests for information

(a) Consumer complaints regarding allegedly unfair trade practices or regarding allegedly false or misleading advertisements should be addressed to the Department of Consumer Protection, Consumer Frauds Division, State Office Building, 165 Capitol Avenue, Hartford, Connecticut 06106.

(b) Consumer complaints concerning foods, drugs, pharmacies, or weights and measures, should be addressed to the Food Division, the Drug Division, the Pharmacy Division, or the Weights and Measures Division, respectively. All of these divisions are located in the State Office Building, 165 Capitol Avenue, Hartford, Connecticut 06106.

(c) Requests for information should be directed preferably to the appropriate division in possession of the information. Requests for information about the department generally should be addressed to the Department of Consumer Protection, Consumer Education Division, State Office Building, 165 Capitol Avenue, Hartford, Connecticut 06106. A nominal fee may be charged for copies of certain statutes and regulations.

(Effective July 27, 1984; Amended March 7, 2008)

Sec. 21a-1-10. Requests for declaratory rulings

(a) Any interested person may present a request for a declaratory ruling from the department regarding the applicability of any statute or regulation administered by the department to any practice described in such request. The request must be in writing and

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submitted by mail or hand-delivered to the office of the commissioner. The facts relating to such request should be in complete and detailed form; the department may demand such additional facts as may be relevant to the requested ruling. The ruling will be made by the department within a reasonable time after the submission of the request and a copy of such ruling will be mailed to the petitioner. In its discretion, the department may hold an informal conference for factfinding purposes relating to such request.

(b) Within 30 days following the receipt of a petition, the commissioner shall determine whether to deny or to grant it. If he denies the petition, he shall notify the petitioner of his decision in writing. If the petition is granted, the commissioner shall make a ruling and send it to the petitioner. Any such ruling shall have the same effect as a final decision in a contested case.

(Effective July 27, 1984)

Part IV

Rule Making Functions

Sec. 21a-1-11. Authority to promulgate regulations

Statutory authority to adopt, amend, or repeal regulations is derived from 4 the various laws administered by the department. These laws include, but are not limited to, the following sections of the General Statutes: 21a-43, 21a-156, 21a-336, and 43-3.

(Effective July 27, 1984; Amended March 7, 2008)

Sec. 21a-1-12. Petition for the promulgation, amendment or repeal of a regulation

Petitions by interested persons requesting the promulgation, amendment, or repeal of a regulation of the department must be submitted to the department in writing. Such petition shall contain an explanation of the person's interest in the particular subject matter and the reasons for the proposal. Within thirty days of the receipt of the petition, the department will either deny the petition in writing, stating its reasons for the denial, or initiate proceedings to effect the requested action.

(Effective July 27, 1984)

Sec. 21a-1-13. Procedure for the issuance, amendment or repeal of a regulation

(a) Proceedings for the issuance, amendment, or repeal of a regulation, including proceedings for the exemption of certain products or classes of products from statutory requirements, may be commenced by the department on its own initiative or pursuant to a petition submitted by an interested person.

(b) Notice of the proposed issuance, amendment, or repeal of a regulation will appear in the Connecticut Law Journal at least twenty days prior to the proposed action. The notice will contain:

- (i) a statement of the purpose of the proposed action;
- (ii) a statement of the time, date and place of the public hearing or other opportunity for

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the presentation of views;

(iii) reference to the statutory authority under which the department is acting; and

(iv) a statement of the terms or substance of the intended action.

(c) Adequate publicity will be provided by the department to assure that all interested parties have notice of the time, date and place of the public hearing or other opportunity for the presentation of views. The purpose is to afford an opportunity for all interested parties to participate in the proceedings through the submission of written or oral data, views, arguments, or suggestions.

(d) After any necessary revisions have been made, the proposed regulations will be forwarded to the attorney general and to the legislative review committee of the General Assembly for approval, as required under sections 4-169 and 4-170 of the General Statutes.

(e) The new regulation or the amendment or repeal of an existing regulation will become final following approval by the attorney general and the legislative review committee and certification thereof to the secretary of state.

(f) When the department finds that an imminent peril to the public health, safety, or welfare so requires, it may adopt emergency regulations, as provided in section 4-168 (b) of the General Statutes.

(Effective July 27, 1984)

Part V

Licensing Function

Sec. 21a-1-14. Authority to issue and revoke licenses

Statutory authority to issue, renew, suspend, or revoke licenses, permits, or registrations is derived from various laws administered by the department. These laws include, but are not limited to, the following sections of the General Statutes: 21a-18, 21a-35, 21a-53, 21a-152, 21-28, and 43-10.

(Effective July 27, 1984; Amended March 7, 2008)

Sec. 21a-1-15. Form, contents and filing of applications

All applications shall include

(i) the name and address of the applicant;

(ii) the name and address of the applicant's counsel, agent, or other representative, if any;

(iii) the purpose for which the application is made;

(iv) any statutes and rules which support the application;

(v) a complete and concise description of the activities, facilities, projects, or other actions for which the license, permit or registration is sought;

(vi) any other information which the department may require; and

(vii) any additional information which the applicant considers relevant.

Applications shall be addressed to the appropriate division of the department and shall

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be sent by mail or hand-delivered during normal business hours.

(Effective July 27, 1984)

Sec. 21a-1-16. Revocation or suspension of licenses

(a) No license, permit, or registration may be suspended or revoked without a prior notice to the licensee detailing the reasons for the proposed suspension or revocation. The licensee shall further be afforded an opportunity to appear for a hearing before the commissioner to show cause why the proposed suspension or revocation is not warranted. Any such hearing shall be conducted as a contested case, as defined in section 21a-1-20 of these regulations.

(b) If the commissioner finds that the public health, safety, or welfare imperatively requires emergency action, a license, permit, or registration may be suspended or revoked without the necessity of a prior hearing. The notice to the licensee shall detail the reasons for the emergency action and shall afford the licensee an opportunity for a subsequent hearing to contest the suspension or revocation.

(c) Any person aggrieved by the decision of the commissioner or his representative in connection with any licensing proceedings may seek review of the decision by initiating an appropriate action in the Superior Court for the Judicial District of Hartford.

(Effective July 27, 1984; Amended March 7, 2008)

Part VI

Investigations and Inspections

Sec. 21a-1-17. Authority to conduct investigations and inspections

Statutory authority to conduct investigations and inspections is derived from various laws administered by the department. Section 21a-11 of the General Statutes confers upon the commissioner of consumer protection and his agents the general authority to enter upon private premises during regular business hours for the purposes of conducting necessary investigations and purchasing samples for analysis. Laws conferring specific authority to conduct investigations and inspections include, but are not limited to, the following sections of the General Statutes: 21a-40, 21a-70, 21a-116, 21a-118, 21a-235, 21a-261, 21a-265, 21a-343, 42-112, and 43-3.

(Effective July 27, 1984; Amended March 7, 2008)

Sec. 21a-1-18. Seizures and condemnations

(a) Statutory authority to seize and/or condemn products which are allegedly adulterated or misbranded is derived from sections 21a-39 and 21a-96 of the General Statutes.

(b) Statutory authority to detain or embargo in intrastate commerce household products which are allegedly banned or misbranded hazardous substances is derived from section 21a-340 of the General Statutes.

(c) Statutory authority to seize and destroy any incorrect weight, measure, or weighing and measuring device is derived from section 43-3 of the General Statutes.

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(d) Whenever an inspector or an investigator obtains a sample of any product for further analysis, he shall pay or offer to pay the owner, operator, or agent in charge for such sample and give a receipt describing the sample obtained. Laws conferring the specific authority to obtain samples include, but are not limited to, the following sections of the General Statutes: 21a-39, 21a-116, and 21a-343.

(Effective July 27, 1984; Amended March 7, 2008)

Part VII

Hearings Procedures

Sec. 21a-1-19—21a-1-27. Repealed

Repealed June 27, 1985.

Sec. 21a-1-19a. Applicability

(a) These hearing procedures shall apply to all Compliance Meetings and Contested Cases held by the Department of Consumer Protection.

(b) As used herein, “agency” means the Department of Consumer Protection.

(c) As used herein, “certificate” includes the whole or part of any Department of Consumer Protection permit which the Department issues under authority of the General Statutes and which (1) authorizes practice of the profession by certified persons but does not prohibit the practice of the profession by others, not certified, (2) prohibits a person from falsely representing that he is certified to practice the profession unless the person holds a certificate issued by the Department, and (3) requires as a condition of certification that a person submit specified credentials to the Department which attest to qualifications to practice the profession.

(d) As used herein, “License” includes the whole or part of any Department of Consumer Protection permit, approval, or similar form of permission which the Department issues under authority of the General Statutes and which requires: (1) practice of the profession by licensed persons only, (2) demonstration of competence to practice by examination or other means and meeting of certain minimum standards, and (3) enforcement of standards by the Department.

(e) As used herein, “registration” includes the whole or part of any permit which the Department issues under authority of the General Statutes and which: (1) requires persons to place their names on a list maintained by the Department before they can engage in the practice of a specified profession or occupation, (2) does not require a person to demonstrate competence by examination or other means, and (3) may be revoked or suspended by the Department for cause.

(Effective June 27, 1985)

Sec. 21a-1-20a. Opportunity to show compliance

(a) No revocation, suspension, annulment or withdrawal of any certificate, license or

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registration is lawful unless prior to the institution of agency proceedings, the agency gave notice by mail to the holder thereof of facts or conduct which warrant the intended action, and the holder thereof was given the opportunity to show compliance with all lawful requirements for the retention of the certificate, license or registration.

(b) The notice of the opportunity to show compliance shall contain:

- (1) A statement of the time, date and method for responding to the agency;
- (2) A reference to the statute(s) or regulation(s) allegedly violated;
- (3) A clear and concise factual statement sufficient to inform each respondent of the acts or practices alleged to be in violation of the law. This requirement may be met by including a copy of the investigation report with the notice; and

(4) A statement that each respondent may be represented by counsel.

(c) The agency may request the respondent to attend a compliance conference as the method for responding to the agency. Compliance conferences shall be informal and the rules of evidence shall not apply. Compliance conferences may be recorded but need not be transcribed.

(d) The Commissioner may, in his or her discretion, designate a person to preside at such compliance conference. After said compliance conference, the designated presiding officer shall report in writing his or her recommendations to the Commissioner.

(Effective August 23, 1993)

Sec. 21a-1-21a. Summary suspension procedures

If the agency finds that public health, safety or welfare imperatively requires emergency action, and incorporates a finding to that effect in its order, summary suspension of a certificate, license, or registration may be ordered pending proceedings for revocation or other action. These proceedings shall be promptly instituted and determined.

(Effective June 27, 1985)

Sec. 21a-1-22a. Contested cases

(a) A “Contested Case” means a proceeding, including but not restricted to rate-making, price fixing, and licensing, in which the legal rights, duties or privileges of a party are required by statute to be determined by an agency after an opportunity for hearing or in which a hearing is in fact held, but does not include hearings referred to in Section 4-168 of the Connecticut General Statutes.

(b) When an agency has reason to believe there has been a violation of the statute(s) or regulation(s) it administers, it shall issue a complaint by certified mail to the respondent.

(c) The notice in contested cases shall contain:

- (1) A statement of the statutory authority and jurisdiction for instituting the proceedings;
- (2) A reference to the specific statutory section(s) or regulations alleged to be violated;
- (3) A short and plain statement of the matters asserted sufficient to inform each respondent of the acts or practices alleged to be in violation of the law;
- (4) Notice of the time, date, place and nature of the hearing; and

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(5) A statement that each respondent may, if he desires, be represented by an attorney.

(d) If a respondent can reasonably show a need for additional time to prepare a defense to the alleged statutory violations, an extension of time may be granted by moving the scheduled hearing to a later date. The granting of such a request is within the complete discretion of the commissioner or such presiding officer as has been designated by the commissioner.

(e) If a respondent can reasonably show that the complaint is unclear or ambiguous as to the nature of the acts in violation of the law, he may file with the agency a written motion for a more detailed statement of the nature of the charges against him. The granting or denial of such a motion is within the complete discretion of the commissioner or such presiding officer as has been designated by the commissioner.

(f) Appearances, Admissions and Denials, Answers, Motions and any other pleading which a Respondent wishes considered by the Commissioner prior to the convening of a contested case proceeding may be filed up to seven days prior to the hearing date. Failure to file any pleadings may allow the agency to proceed with the matter. However, if a Respondent can reasonably show a need for additional time to submit documentation, an extension of time may be granted. The granting of such a request is within the complete discretion of the Commissioner or such presiding officer as has been designated by the Commissioner.

(Effective June 27, 1985)

Sec. 21a-1-23a. Pre-hearing procedure in contested cases

(a) Any time after the issuance of a complaint and before the scheduled hearing date, the commissioner may order or a respondent may request an informal pre-hearing conference. The granting or denial of a request for a pre-hearing conference is within the complete discretion of the commissioner or such presiding officer as has been designated by the commissioner.

(b) A pre-hearing conference may be held for any of the following purposes:

(1) to narrow the scope of the issues in dispute;

(2) to obtain stipulations as to matters of fact;

(3) to stipulate as to the authenticity of documents which are to be offered in evidence;

(4) to stipulate as to the qualifications of any expert witnesses who are to testify at the hearing; and

(5) to discuss the possibility of an informal disposition of the complaint.

(c) A pre-hearing conference need not be recorded, but a written record will be made of any stipulations as to matters of fact, as to the authenticity of documents, or as to the qualifications of expert witnesses. Any such written record will be signed by each of the individual respondents or his counsel and by the commissioner or his authorized representative.

(Effective June 27, 1985)

Sec. 21a-1-24a. Conduct of adjudicative hearings in contested cases

(a) Hearings in contested cases shall be presided over by the commissioner or his designated hearing officer.

(b) Said commissioner or hearing officer shall have the power to:

(1) Regulate the course of the hearing and the conduct of the parties and their counsel therein;

(2) Insure that all testimony is given under oath;

(3) Rule upon offers of proof and to receive evidence;

(4) Consider and rule upon all motions; and

(5) Require any additional written and/or oral argument.

(c) Each party in an adjudicative hearing shall have the right to present evidence, cross examine witnesses, enter motions and objections, and assert all other rights essential to a fair hear.

(d) Intervention by interested parties shall be permitted in any contested case, as provided by applicable statute or otherwise within the discretion of the commissioner or hearing officer.

(e) All adjudicative hearings in contested cases shall be recorded and shall be conducted in accordance with the provisions of chapter 54 of the General Statutes.

(Effective June 27, 1985)

Sec. 21a-1-25a. Transcript of the proceedings

(a) At the close of the reception of evidence, the respondent or any other party of record may file a written request addressed to the agency for a written transcript of the proceedings. If no such written request is filed, the agency may order that a written transcript be prepared.

(b) If any party of record desires a copy of the transcript, it will be made available to him upon written request and the tendering of the appropriate cost.

(Effective June 27, 1985)

Sec. 21a-1-26a. Informal disposition in contested cases

(a) Unless precluded by law, informal disposition may be made of any contested case by stipulation, agreed settlement, consent order, or default. A respondent may agree to enter an agreement containing a consent order in lieu of a hearing on the issue(s). Such agreement may be negotiated by the respondent and the complaint counsel or authorized representative of said agency. The acceptance of a consent agreement is within the complete discretion of the commissioner.

(b) A consent agreement shall contain:

(1) An admission of all jurisdictional facts;

(2) An express waiver of the right to seek judicial review or otherwise challenge or contest the validity of the order;

(3) An express waiver of the requirement that the decision of said commissioner contain findings of fact and conclusion of law;

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- (4) A provision that the complaint may be used in construing the terms of the order;
- (5) A statement that the order contained therein shall have the same force and effect as an order entered after a full hearing and shall become final when issued;
- (6) A statement that said order shall not be effective unless and until accepted and approved by the commissioner;
- (7) The signature of each respondent or his attorney and the complaint counsel; and
- (8) The signature of the commissioner accepting and approving the consent agreement.

(Effective June 27, 1985)

Sec. 21a-1-27a. Proposal for decision

When in a contested case the Commissioner has not heard the case or read the record, the decision, if adverse to a party to the proceeding other than the agency itself, shall not be made until a proposal for decision is served upon the parties and an opportunity is afforded to each party adversely affected to file exceptions and present briefs and oral argument to the commissioner. The proposal for decision shall contain a statement of the reasons therefore, and of each issue of fact or law necessary to the proposed decision, prepared by the person who conducted the hearing or one who has read the record. The parties by written stipulation may waive compliance with this section.

(Effective June 27, 1985)

Sec. 21a-1-28a. Final decision in a contested case

(a) The final decision or order in a contested case shall be rendered by the commissioner after due consideration of the entire record. If no written request was filed for the preparation of a transcript, a final decision may be rendered at any time following the close of the hearing. If a transcript was requested in writing, the final decision may be rendered within a reasonable time following preparation of the transcript.

(b) A final decision or order adverse to a party in a contested case shall be in writing or stated in the record.

(c) Parties shall be notified either personally or by mail of any decision or order. Upon request, a copy of the text of the final decision or order shall be sent by mail to each of the respondents and respondent's counsel, and to any other party of record.

(d) The agency shall proceed with reasonable dispatch to conclude any matter pending before it and shall render a final decision in all contested cases within ninety days following the close of evidence and filing of briefs in such proceedings.

(Effective June 27, 1985)

Sec. 21a-1-29a. Inconsistent regulations

Unless precluded by law, the regulations appearing as Sections 21a-1-19a through 21a-1-28a inclusive, shall take precedence over any other conflicting or inconsistent regulation pertaining to hearing procedures within the Department of Consumer Protection.

(Effective June 27, 1985)

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Subject

Uniform Rules of Procedure Concerning Boards and Commissions within Its Jurisdiction

Inclusive Sections

§§ 21a-9-1—21a-9-11

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Sec. 21a-9-11.	Inconsistent regulations

Uniform Rules of Procedure Concerning Boards and Commissions within Its Jurisdiction

Sec. 21a-9-1. Applicability

(a) The uniform hearing procedures shall apply to all boards and commissions within the Department of Consumer Protection pursuant to Section 21a-6 of the General Statutes.

(b) As used herein, “agency” means the boards or commissions transferred to the Department of Consumer Protection pursuant to Section 21a-6 of the General Statutes.

(c) As used herein, “certificate” includes the whole or part of any Department of Consumer Protection permit which the Department issues under authority of the General Statutes and which (1) authorizes practice of the profession by certified persons but does not prohibit the practice of the profession by others, not certified, (2) prohibits a person from falsely representing that he is certified to practice the profession unless the person holds a certificate issued by the Department and (3) requires as a condition of certification that a person submit specified credentials to the Department which attest to qualifications to practice the profession.

(d) As used herein, “License” includes the whole or part of any Department of Consumer Protection permit, approval, or similar form of permission which the Department issues under authority of the General Statutes and which requires; (1) practice of the profession by licensed persons only, (2) demonstration of competence to practice by examination or other means and meeting of certain minimum standards and (3) enforcement of standards by the Department or Agency.

(e) As used herein, “registration” includes the whole or part of any permit which the Department issues under authority of the General Statutes and which; (1) requires persons to place their names on a list maintained by the Department before they can engage in the practice of a specified profession or occupation, (2) does not require a person to demonstrate competence by examination or other means and (3) may be revoked or suspended by the Agency for cause.

(f) As used herein, “practitioner” includes any person possessing a certificate, license, or registration which the Department issues under authority of Section 21a-8 (5) of the General Statutes pertaining to the boards and commissions within the Department of Consumer Protection pursuant to Section 21a-6 of the General Statutes.

(Effective February 22, 1984)

Sec. 21a-9-2. Opportunity to show compliance

(a) No revocation, suspension, annulment or withdrawal of any certificate, license or registration is lawful unless prior to the institution of agency proceedings, the agency gave notice by mail to the practitioner of facts or conduct which warrant the intended action, and the practitioner was given the opportunity to show compliance with all lawful requirements for the retention of the certificate, license or registration.

(b) The notice of the opportunity to show compliance shall contain:

(1) A statement of the time, date and method for responding to the agency;

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- (2) A reference to the statute(s) or regulation(s) allegedly violated;
 - (3) A clear and concise factual statement sufficient to inform each respondent of the acts or practices alleged to be in violation of the law. This requirement may be met by including a copy of the investigation report with the notice; and
 - (4) A statement that each respondent may be represented by counsel.
- (c) The agency may request the respondent to attend a compliance conference as the method for responding to the agency. Compliance conferences shall be informal and the rules of evidence shall not apply. Compliance conferences may be recorded but need not be transcribed.
- (d) The agency may, in its discretion, designate a person, other than a member of said agency, to preside at such compliance conference. After said compliance conference, the designated presiding officer shall report in writing his or her recommendations to the agency.

(Effective August 23, 1993)

Sec. 21a-9-3. Summary suspension procedures

If the agency finds that public health, safety or welfare imperatively requires emergency action, and incorporates a finding to that effect in its order, summary suspension of a certificate, license, or registration may be ordered pending proceedings for revocation or other action. These proceedings shall be promptly instituted and determined.

(Effective February 22, 1984)

Sec. 21a-9-4. Contested cases

(a) A "Contested Case" means a proceeding, including but not restricted to rate-making price fixing and licensing, in which the legal rights, duties or privileges of a party are required by statute to be determined by an agency after an opportunity for hearing or in which a hearing is in fact held, but does not include hearings referred to in Section 4-168 of the Connecticut General Statutes.

(b) When an agency has reason to believe there has been a violation of the statute(s) or regulation(s) it administers, it shall issue a complaint by certified mail to the respondent.

(c) The notice in contested cases shall contain:

- (1) A statement of the statutory authority and jurisdiction for instituting the proceedings;
- (2) A reference to the specific statutory section(s) or regulations alleged to be violated;
- (3) A short and plain statement of the matters asserted sufficient to inform each respondent of the acts or practices alleged to be in violation of the law;
- (4) Notice of the time, date, place and nature of the hearing; and
- (5) A statement that each respondent may, if he desires, be represented by an attorney.

(d) (1) If a respondent can show a need for additional time to prepare a defense to the alleged violations, an extension of time may be granted by moving the scheduled hearing to a later date. The granting of such a request is within the complete discretion of the agency or such presiding officer as has been designated by the agency.

(2) If a respondent can show that the complaint is unclear or ambiguous as to the nature

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of the acts in violation of the law, he may file with the agency a written motion for a more detailed statement of the nature of the charges against him. The granting or denial of such a motion is within the complete discretion of the agency or such presiding officer as has been designated by the agency.

(3) Any pleading which a Respondent wishes considered by the agency prior to the convening of a contested case proceeding may be filed up to seven days prior to the hearing date. If a Respondent can show a need for additional time to submit documentation, an extension of time may be granted. The granting of such a request is within the complete discretion of the agency or such presiding officer as has been designated by the agency.

(Effective September 22, 1988)

Sec. 21a-9-5. Conduct of adjudicative hearings in contested cases

(a) Hearings in contested cases shall be presided over by the appropriate agency, its designated hearing panel, or hearing officer.

(b) Said agency, designated hearing panel or hearing officer shall have the power to:

(1) Regulate the course of the hearing and the conduct of the parties and their counsel therein;

(2) Insure that all testimony is given under oath;

(3) Rule upon offers of proof and to receive evidence;

(4) Consider and rule upon all motions; and

(5) Require any additional written and/or oral argument.

(c) Each party in an adjudicative hearing shall have the right to present evidence, cross examine witnesses, enter motions and objections, and assert all other rights essential to a fair hearing.

(d) Intervention by interested parties shall be permitted in any contested case, as provided by applicable statute or otherwise within the discretion of the agency, designated hearing panel or hearing officer.

(e) All adjudicative hearings in contested cases shall be recorded and shall be conducted in accordance with the provisions of chapter 54 of the General Statutes.

(Effective February 22, 1984)

Sec. 21a-9-6. Transcript of the proceedings

(a) At the close of the reception of evidence, the respondent or any other party of record may file a written request addressed to the agency for a written transcript of the proceedings. If no such written request is filed, the agency may order that a written transcript be prepared.

(b) If any party of record desires a copy of the transcript, it will be made available to him upon written request and the tendering of the appropriate cost.

(Effective February 22, 1984)

Sec. 21a-9-7. Informal disposition in contested cases

(a) Unless precluded by law, informal disposition may be made of any contested case

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by stipulation, agreed settlement, consent order, or default. A respondent may agree to enter an agreement containing a consent order in lieu of a hearing on the issue(s). Such agreement may be negotiated by the respondent and the complaint counsel or authorized representative of said agency provided that said authorized representative shall not be a member of said agency. The acceptance of a consent agreement is within the complete discretion of the agency and prior to exercising such discretion the agency may designate a member independently to confer with the parties and then present to the agency hearing panel a recommendation whether to accept or reject such agreement, provided that in order to avoid prejudice the reasons forming the basis for such recommendation shall not be disclosed to such panel, and such member making the recommendation shall not be a member of the agency hearing panel rendering the decision.

(b) A consent agreement shall contain:

- (1) An admission of all jurisdictional facts;
- (2) An express waiver of the right to seek judicial review or otherwise challenge or contest the validity of the order;
- (3) An express waiver of the requirement that the decision of said board or commission contain findings of fact and conclusion of law;
- (4) A provision that the complaint may be used in construing the terms of the order;
- (5) A statement that the order contained therein shall have the same force and effect as an order entered after a full hearing and shall become final when issued;
- (6) A statement that said order shall not be effective unless and until accepted and approved by said agency;
- (7) The signature of each respondent or his attorney; and
- (8) The signature of said agency chairman-accepting and approving the consent agreement.

(Effective February 22, 1984)

Sec. 21a-9-8. Proposal for decision

When in a contested case a majority of the officials of the agency who are to render the final decision have not heard the case or read the record, the decision if adverse to a party to the proceeding other than the agency itself, shall not be made until a proposal for decision is served upon the parties and an opportunity is afforded to each party adversely affected to file exceptions and present briefs and oral argument to the officials who are to render the decision. The proposal for decision shall contain a statement of the reasons therefore, and of each issue of fact or law necessary to the proposed decision, prepared by the person who conducted the hearing or one who has read the record. The parties by written stipulation may waive compliance with this section.

(Effective February 22, 1984)

Sec. 21a-9-9. Final decision in a contested case

- (a) The final decision or order in a contested case shall be rendered by an agency after

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due consideration of the entire record. If no written request was filed for the preparation of a transcript, a final decision may be rendered at any time following the close of the hearing. If a transcript was requested in writing, the final decision may be rendered within a reasonable time following preparation of the transcript.

(b) A final decision or order adverse to a party in a contested case shall be in writing or stated in the record.

(c) Parties shall be notified either personally or by mail of any decision or order. Upon request, a copy of the text of the final decision or order shall be sent by mail to each of the respondents and respondent's counsel, and to any other party of record.

(d) The agency shall proceed with reasonable dispatch to conclude any matter pending before it and shall render a final decision in all contested cases within ninety days following the close of evidence and filing of briefs in such proceedings.

(Effective February 22, 1984)

Sec. 21a-9-10. Petitions

(a) Any interested person may petition the commissioner of consumer protection requesting the promulgation, amendment or repeal of a regulation pursuant to Section 4-174 of the General Statutes and Section 19-170a-12 of the Regulations of Connecticut State Agencies pertaining to an agency within the jurisdiction of the Department of Consumer Protection. Only written petitions will be considered. The petition shall set forth clearly the reasons for its submission.

(b) Petitions for declaratory rulings on the applicability of any statutory provision within the Department of Consumer Protection pertaining to boards or commissions shall be submitted in writing to the appropriate board or commission pursuant to Section 4-176 of the General Statutes. A copy of such request shall also be simultaneously made to the Commissioner of Consumer Protection.

(Effective February 22, 1984)

Sec. 21a-9-11. Inconsistent regulations

Unless precluded by law the regulations appearing as Sections 21a-9-1 through 21a-9-10, inclusive, shall take precedence over any other conflicting or inconsistent regulation pertaining to hearing procedures of all boards and commissions within the Department of Consumer Protection pursuant to Section 21a-6 of the General Statutes.

(Effective February 22, 1984)

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Schedule for License Renewal

Section

§ 21a-10-1

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Sec. 21a-10-1. Schedule for license renewal

Schedule for License Renewal

Sec. 21a-10-1. Schedule for license renewal

Licenses, certificates, registrations, and permits issued by the Department of Consumer Protection shall be renewed and expire annually pursuant to the following schedule.

(a) Licenses, certificates, registrations, and permits that expire annually on the last day of the month of December and renew on the first day of the month of January:

- (1) frozen dessert manufacturer-retail;
- (2) frozen dessert manufacturer-wholesale;
- (3) interior designer;
- (4) license to advertise and sell property in another state;
- (5) mobile manufactured home park;
- (6) mobile manufactured home seller;
- (7) sale of nonlegend drugs;
- (8) refrigerated locker; and
- (9) weights and measures dealer and repairer.

(b) Licenses, certificates, registrations, and permits that expire annually on the last day of the month of January and renew on the first day of the month of February:

- (1) arborist;
- (2) community association manager;
- (3) controlled substance laboratory;
- (4) land surveyor;
- (5) pharmacist;
- (6) professional engineer; and
- (7) professional engineer and land surveyor.

(c) Licenses, certificates, registrations, and permits that expire annually on the last day of the month of February and renew on the first day of the month of March:

- (1) controlled substance registration for practitioner.

(d) Licenses, certificates, registrations, and permits that expire annually on the last day of the month of March and renew on the first day of the month of April:

- (1) pharmacy technician; and
- (2) real estate broker.

(e) Licenses, certificates, registrations, and permits that expire annually on the last day of the month of April and renew on the first day of the month of May:

- (1) architect and land surveyor corporation;
- (2) automatic fire sprinkler system layout technician;
- (3) bedding — manufacturer;
- (4) bedding — renovator;
- (5) bedding — secondhand dealer;
- (6) bedding — sterilization;
- (7) bedding — supply dealer;
- (8) non water well contractor;

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- (9) non water well driller;
 - (10) professional engineer and architect corporation;
 - (11) professional engineer, architect, and land surveyor corporation;
 - (12) professional engineer and land surveyor corporation;
 - (13) real estate appraiser — certified;
 - (14) real estate appraiser — licensed;
 - (15) real estate appraiser — provisional licensed;
 - (16) real estate appraiser — tenured licensed;
 - (17) water well driller; and
 - (18) water well contractor.
- (f) Licenses, certificates, registrations, and permits that expire annually on the last day of the month of May and renew on the first day of the month of June:
- (1) real estate salesperson.
- (g) Licenses, certificates, registrations, and permits that expire annually on the last day of the month of June and renew on the first day of the month of July:
- (1) apple juice and cider;
 - (2) bakery;
 - (3) general contractor;
 - (4) major subcontractor;
 - (5) manufacturer of controlled substances;
 - (6) manufacturer of drugs, medical devices or cosmetics;
 - (7) non-alcoholic beverage;
 - (8) public weigher;
 - (9) vending;
 - (10) wholesaler of controlled substances; and
 - (11) wholesaler of drugs, medical devices or cosmetics.
- (h) Licenses, certificates, registrations, and permits that expire annually on the last day of the month of July and renew on the first day of the month of August:
- (1) architect;
 - (2) architect corporation;
 - (3) landscape architect; and
 - (4) weights and measurers device.
- (i) Licenses, certificates, registrations, and permits that expire annually on the last day of the month of August and renew on the first day of the month of September:
- (1) elevator contractor — all categories and types;
 - (2) elevator journeyman — all categories and types;
 - (3) heating, cooling and piping contractor — all categories and types;
 - (4) heating, cooling and piping journeyman — all categories and types;
 - (5) mechanical contractor;
 - (6) pharmacy;
 - (7) television and radio repair dealer — all categories and types; and

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- (8) television and radio repair technician — all categories and types.
- (j) Licenses, certificates, registrations, and permits that expire annually on the last day of the month of September and renew on the first day of the month of October:
 - (1) electrical contractor — all categories and types;
 - (2) electrical journeyman — all categories and types; and
 - (3) health club.
- (k) Licenses, certificates, registrations, and permits that expire annually on the last day of the month of October and renew on the first day of the month of November:
 - (1) fire protection contractor — all categories and types;
 - (2) fire protection journeyman — all categories and types;
 - (3) plumbing contractor — all categories and types;
 - (4) plumbing journeyman — all categories and types;
 - (5) motor fuel quality; and
 - (6) retail gasoline dealer.
- (l) Licenses, certificates, registrations, and permits that expire annually on the last day of the month of November and renew on the first day of the month of December:
 - (1) home improvement contractor; and
 - (2) home improvement salesman.

(Effective January 3, 1995; Amended February 22, 2000; Amended March 7, 2008)

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Subject

Use of Chemicals in Removing Soot from Boilers, Furnaces, Chimneys and Flues

Inclusive Sections

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Sec. 21a-12-3.	Applicant to furnish sample of compound
Sec. 21a-12-4.	Permit number to be printed on packages of compound

Use of Chemicals in Removing Soot from Boilers, Furnaces, Chimneys and Flues

Sec. 21a-12-1. Application for permission to manufacture or distribute

Any person, firm or corporation desiring to manufacture and/or distribute for the removal of soot from boilers, furnaces, chimneys and flues in the state of Connecticut shall make application in duplicate on forms furnished by the commissioner.

(Effective July 27, 1984)

Sec. 21a-12-2. Fee

Such application shall be accompanied by the statutory fee of fifty dollars.

(Effective July 27, 1984)

Sec. 21a-12-3. Applicant to furnish sample of compound

Each applicant shall furnish a sample, at least one pound in weight, of the compound which he proposes to distribute and shall, at the same time, give a list of the component elements in such compound and their proportions.

(Effective July 27, 1984)

Sec. 21a-12-4. Permit number to be printed on packages of compound

Each permit shall have a serial number which number shall be imprinted on each package of any such compound sold or offered for sale in the state of Connecticut and in the following form; to wit,

Permit No.

State of Connecticut

Department of Consumer Protection

Hartford

(Effective July 27, 1984)

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Subject

Guidelines for Public Playground Equipment

Inclusive Sections

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Guidelines for Public Playground Equipment

Sec. 21a-12a-1. Definitions

For the purposes of Section 21a-12a-2 of these regulations, the term “playground equipment” shall mean equipment intended for use by children in any area of a park, school or public playground owned by a city, town, borough, consolidated town and city, consolidated town and borough, municipal corporation, school district, regional district or other district or other political subdivision of the state of Connecticut.

(Adopted effective May 31, 1996)

Sec. 21a-12a-2. Guidelines for playground equipment

The guidelines for playground equipment adopted by the United States Consumer Product Safety Commission in its Handbook for Public Playground Safety are adopted, and herein incorporated by reference, as voluntary guidelines for playground equipment in this state. The recommended timetable to meet these voluntary guidelines is January 1, 1997. Copies of the Handbook for Public Playground Safety may be obtained by contacting the Department of Consumer Protection through the appropriate telephone number, e-mail address, mailing address or physical address listed on the department’s internet website: www.ct.gov/dcp.

(Adopted effective May 31, 1996; Amended July 10, 2017)

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Compliance with Flour Enrichment Standards

Inclusive Sections

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Sec. 21a-29-1.	Exceptions
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Compliance with Flour Enrichment Standards

Sec. 21a-29-1. Exceptions

The terms of Connecticut General Statutes, Section 21a-28 (a) shall not apply to flour sold to distributors, brokers or other processors, if the purchaser furnishes the seller a certificate, certifying that the flour will be (1) resold to a distributor, broker or other processor, or (2) used in the manufacture, mixing or compounding of white bread or rolls enriched to meet the requirements of the Connecticut General Statutes, Section 21a-28, or (3) used for the manufacture, mixing or compounding of pastry products or other products not required to be enriched by Section 21a-28 of the Connecticut General Statutes. It shall be unlawful for any such purchaser so furnishing any such certificate to use or resell the flour purchased in any manner other than as prescribed by this act or by regulations adopted thereunder.

(Effective July 27, 1984)

Sec. 21a-29-2. Certificate

(a) The certificate to be used in compliance with Sec. 21a-29-1 of these regulations shall be as follows:

FLOUR PURCHASER’S CERTIFICATE

Purchaser	Address
Hereby acknowledges that from this date all unenriched flour purchased from	
Seller	Address

will be:

- 1) Resold to a distributor, broker or other processor, or
- 2) Used in the manufacture, mixing or compounding of white bread or rolls enriched to meet the requirements of the Connecticut General Statutes, Section 21a-28.
- 3) Used for the manufacture, mixing or compounding of pastry products or other products not required to be enriched by Section 21a-28 of the Connecticut General Statutes.

Purchaser	Address
Dated this _____ day of _____, 19____.	

(b) The purchaser and seller shall keep a copy of all such certificates for a period of at

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least one year.

(Effective July 27, 1984)

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Frozen Dessert Products Standards and Regulations

Inclusive Sections

§§ 21a-58-1—21a-58-37

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- Sec. 21a-58-27. Quiescently frozen dairy confection: identity; label statement
- Sec. 21a-58-28. Frozen dietary dairy dessert: identity; label statement
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Frozen Dessert Products Standards and Regulations

Sec. 21a-58-1. Grades for frozen desserts

Frozen desserts sold by grade names, such as “Certified” or “Grade A,” shall be manufactured in accordance with the Connecticut standards, and the dairy products used therein shall be of the grade indicated.

(Effective July 27, 1984)

Sec. 21a-58-2. Premises

The building in which frozen desserts and/or frozen dessert mix are manufactured or handled, and the surroundings, shall be maintained in a clean and orderly manner, with the yards well drained, free from refuse, odors, dust or other unsanitary conditions.

(Effective July 27, 1984)

Sec. 21a-58-3. Manufacturing and handling rooms

(a) Rooms in which frozen desserts and/or frozen dessert mix are manufactured or handled shall be adequately ventilated and lighted. Walls and ceilings shall have a smooth, washable, light-colored surface and shall be kept clean. The floor shall be smooth, impervious to water and in good repair and shall be kept clean. Where necessary, adequate pitch to the floor and properly trapped drains shall be provided. Rooms shall be kept free from flies. Hardening rooms shall be equipped with a bell, buzzer, telephone or similar device, to insure the safe exit of persons entering a hardening room. Other types of safety devices may be used upon approval by the commissioner.

(b) All storage rooms, boxes and cabinets shall be so constructed that they can be maintained in a clean and sanitary condition, free from objectionable odors. Cartons, supplies and materials shall be protected in storage against dust, dirt and vermin. All ingredients, except those in watertight containers, shall be stored above the floor, and containers shall be kept covered, except when ingredients are actually being removed.

(Effective July 27, 1984)

Sec. 21a-58-4. Equipment

(a) All utensils and equipment, used in the manufacturing or handling of frozen desserts and/or frozen dessert mix, shall be of a design capable of being readily taken apart for the washing of all parts with which frozen desserts and/or frozen dessert mix come in contact. Welded pipe lines with smooth surface joints and other cleaning-in-place installations, which have been approved by the commissioner, are excepted. Approval for cleaning-in-place installations shall be granted only after request has been received in writing by the commissioner. Frozen desserts and/or frozen dessert mix utensils shall be of smooth, nonabsorbent, stainless steel or equally corrosion-resistant material and shall have flush seams. No utensils which are badly worn, rusted or corroded or which cannot be rendered clean and sanitary by washing shall be used.

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(b) Sanitary piping, connections, fittings and joints shall be of such diameter and so designed as to permit easy cleaning with a brush. One-inch sanitary piping may be used in lengths not exceeding six feet.

(c) Work benches used in the manufacturing or processing of frozen desserts and/or frozen dessert mix shall be metal, so constructed that they can be kept in clean, sanitary condition.

(d) Batch type pasteurizers shall be equipped with flush, leak-protector valves.

(e) Surface coolers shall be equipped with covers unless the cooler is in a separate room used exclusively for cooling.

(f) All strainers shall be of perforated metal.

(Effective July 27, 1984)

Sec. 21a-58-4a. Heat treatment dispensing freezer

(a) **Definitions**, as used in this section and section 21a-58-5:

(1) “Heat Treatment Dispensing Freezer” means a self-contained dispensing freezer with a product reservoir that processes, freezes, and maintains microbiological quality by elevating the temperature of the product using heating methods that are an integral part of the dispensing freezer.

(2) “Lockout” means the mechanical shutdown of the unit and the inability to dispense frozen products.

(3) “Heat Treatment Cycle” means a cycle during which the unit elevates the product temperature, maintains it at a prescribed temperature and time interval, then cools it to an acceptable product holding temperature.

(b) **A heat treatment dispensing freezer shall:**

(1) Provide a visual message that clearly indicates:

(A) The time interval since its last heat treatment cycle;

(B) The period of time that its product was maintained at a temperature above 150° during the most recent heat treatment cycle;

(C) The number of heat treatment cycles completed since its most recent disassembly; and

(D) The hopper and freezing cylinder temperatures.

(2) Have an automatic temperature device which is accurate to plus or minus 3° F.

(3) Complete a heat treatment cycle not less than once each 24 hours.

(4) Maintain its product at a temperature of not less than 150° F for not less than 30 consecutive minutes in each heat treatment cycle.

(5) Maintain a hopper temperature of not more than 41° F when not going through a heat treatment cycle.

(6) Have a heat up time which will not exceed 1-1/2 hours and a cool down time which will not exceed 2 hours.

(7) Provide a safety lock-out device which cannot be reset without complete disassembly of the machine, and prevent frozen product from being dispensed due to any one of the

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following conditions:

- (A) the heat treatment cycle is not properly completed;
- (B) the heat treatment cycle has not been completed once in 24 hours; or
- (C) the heat treatment dispensing freezer has not been disassembled for cleaning and sanitizing in strict compliance with manufacturer's operating instructions and specifications.

(Adopted effective February 6, 1996)

Sec. 21a-58-5. Manufacturing practices

(a) All utensils and equipment, used in the manufacturing and handling of frozen desserts and/or frozen dessert mix, shall be completely dismantled after each days operation, except as provided in subsection (e) of this section or except equipment cleaned in place by prior approval before installation, and all parts with which frozen desserts and/or frozen dessert mix come in contact shall be thoroughly washed with hot water and a cleaning solution. All such utensils and equipment, after assembling, shall be effectively sanitized immediately before use.

(b) Hot and cold running water, and necessary wash sinks of suitable size and construction, for the proper cleaning of all utensils and equipment shall be provided.

(c) Convenient hand-washing facilities, including warm running water, washing detergents, single service towels and/or mechanical hand dryers, shall be provided in all manufacturing rooms.

(d) All multi-service cans, when empty, and before being returned to a frozen dessert and/or frozen dessert mix plant, shall be effectively washed, and shall again be washed and sanitized before refilling.

(e) Heat treatment dispensing freezers shall be cleaned and sanitized in strict compliance with manufacturer's operating instructions hood specifications.

(Effective July 27, 1984; Amended February 6, 1996)

Sec. 21a-58-6. Toilets and lockers

Adequate toilet and locker facilities shall be provided for employees. No toilet room shall open directly into any room used for the manufacturing of frozen desserts and/or frozen dessert mix, unless the toilet room has a vent exhaust system that vents the air in the toilet room directly outside the premises. The vent exhaust system must be of such design as to be activated when someone enters the toilet room. The vent exhaust system must be able to draw fresh air from either inside the premises or outside the premises. Toilet doors shall be equipped with self-closing devices. Wash basins shall be provided with an adequate supply of hot and cold running water, washing detergents, single service towels and/or mechanical hand dryers.

(Effective July 27, 1984)

Sec. 21a-58-7. Health and habits of employees

- (a) All persons engaged in the manufacturing or handling of frozen desserts and/or frozen

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dessert mix shall be free from communicable disease, shall be clean of person and shall wear clean, washable outer clothing.

(b) The use of tobacco or other unsanitary habits are prohibited.

(c) Articles of wearing apparel, when not in use, shall be kept in rooms other than those in which frozen desserts and/or frozen dessert mix are manufactured or handled.

(Effective July 27, 1984)

Sec. 21a-58-8. Bacterial standard

No frozen dessert shall contain more than one hundred thousand standard plate count colonies or more than ten coliform organisms per gram based on standard methods for the examination of dairy products published by the American Public Health Association.

(Effective July 27, 1984)

Sec. 21a-58-9. Labeling

(a) When bakery products or coatings are combined with frozen desserts, as is the case with ice cream sandwiches, ice cream cake roll, coated bars, coated novelties and similar products, in addition to other labeling requirements, the ingredients of such bakery products and coatings shall be clearly declared on the container or label.

(b) The use of the term “home made” or “home maid” and “farm made” or “farm maid” is limited to those products actually manufactured in the home or on the farm.

(Effective July 27, 1984)

Sec. 21a-58-10. Mobile units

(a) “Mobile unit” is defined as any vehicle on which frozen desserts are manufactured, prepared, processed or converted and which is used in selling and dispensing frozen desserts to the consuming public.

(b) Mobile units shall comply with sections 21a-58-1 to 21a-58-9, inclusive, with the exception of those regulations pertaining to manufacturing and handling rooms, pasteurization and toilet rooms. All mobile units shall be kept in an orderly and sanitary condition at all times. In addition to said regulations with which mobile units shall comply, they shall also comply with the following regulations.

(c) Mobile unit interiors shall be of sufficient size with equipment and fixtures conveniently located so as to eliminate needless steps for operation of equipment and serving of customers. A potable water supply tank, having a minimum capacity of twenty gallons, heated electrically or otherwise and tilted toward a capped drain cock, shall be provided. The water inlet pipe shall be of removable flexible copper or other approved tubing with a nozzle for the hose connection capped when not being used. Hose for connection to a potable water supply shall be provided and be equipped with an approved vacuum breaker and check valve. A double compartment sink supplied with running hot and cold water which shall have a swivel faucet shall be provided and it shall be large enough to accommodate the largest piece of equipment to be cleansed therein.

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(d) A hand wash sink, seamless, with running hot and cold water, detergent and single service or individual towels, or mechanical hand dryer, shall be provided.

(e) A suitable waste tank with a capacity at least equal to that of the water supply tank shall be provided, tilted toward a drain cock, with an adequate method of gauging the contents. It shall be emptied and flushed as often as necessary, and in a sanitary manner, in order to maintain sanitary conditions.

(f) A refrigerated box with mechanical refrigeration, capable of maintaining a temperature at 40°F. or lower, shall be provided. It shall be constructed of stainless steel or other noncorrosive material, properly drained, and of adequate capacity for the storage of food products.

(g) Floors shall be of metal or similar approved material and properly sloped. Junctures of floor, wall and adjoining fixtures shall be watertight and coved.

(h) Frozen dessert mix shall be packaged in containers approved by the commissioner.

(i) The vehicle shall be of sound construction; that part containing the products, preferably of an acceptable metal, shall be entirely enclosed and kept in a sanitary condition both inside and outside at all times. The truck shall be thoroughly and efficiently insulated, with all openings screened and glass enclosed. The products-containing compartment of the truck shall have adequate working space to avoid overcrowding. Floors, walls and ceilings thereof shall be constructed of an acceptable impervious material; the floors shall be properly drained; the truck shall be provided with adequate light and ventilation. A metal refuse container with suitable cover shall be provided inside the vehicle. The outside of the mobile unit shall be equipped with a suitable waste container for the depositing of cups, cones, napkins, etc. by patrons. Separation by partition, self-closing doors excepted, shall be made between the driver's seat and manufacturing unit unless the vehicle is air-conditioned. Persons handling frozen desserts or engaged in the manufacture thereof shall be clothed in white, clean, washable uniforms.

(j) A mobile unit shall be used only for the manufacture and sale of frozen desserts unless specific exemption is applied for in writing and granted by the commissioner for the sale by such unit of other food products. Such permission shall appear on the license granted to such mobile unit.

(Effective July 27, 1984)

Sec. 21a-58-11. Depots

(a) "Depot" is defined as a building from which mobile units operate and where they are sanitized.

(b) All mobile units shall operate from a depot and shall report to their respective depots for sanitizing at least once a day except those operating exclusively at fairs, outings and carnivals for a short duration. (1) The walls of the sanitizing area shall be smooth, clean and washable. (2) There shall be no openings in the walls or at the base of the door, in order to prevent vermin infestation. The floor shall be constructed of cement or other impervious material, provided with a drain, and coved at the junction of the floor and wall. (3) There

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shall be adequate light and ventilation provided and the interior and exterior of the structure shall be kept in an orderly and sanitary condition at all times. (4) A sufficient supply of hot and cold running water shall be provided.

(c) For washing purposes there shall be an adequate sink or sinks, each of which shall be large enough to accommodate the largest piece of equipment to be washed. Sinks shall be provided with drainboards of impervious material other than wood. (1) A hose and hose connection shall be provided as well as a method of hanging hose for draining to prevent contamination. (2) A metal pipe-drying rack for utensils shall be provided. (3) Clothes lockers and metal refuse containers with suitable covers shall be provided. (4) A physical separation between the truck premises and the area where food is stored shall be required. This separation may be a dwarf partition. (5) Adequate suitable toilet facilities shall be provided.

(d) A refrigerated box with mechanical refrigeration capable of maintaining a temperature of 40°F. or lower shall be provided for the storage of surplus frozen dessert mix and/or any other perishable commodity. Suitable storage space for nonperishable foods, packaging material, napkins, etc. shall be provided to prevent contamination.

(e) Any change in the location of the depot from which units operate shall be reported to and approved by the commissioner of consumer protection before operations can be instituted at the new depot.

(f) Depots shall be provided with suitable waste disposal facilities. The disposal of liquid wastes shall be to the public sewerage system if available and permitted by local ordinance, or to a properly designed and installed private facility. Private liquid waste treatment facilities shall be approved by the local health director. Waste tanks shall be emptied only into depot facilities.

(Effective July 27, 1984)

Sec. 21a-58-12. Milk shake mix

Milk shake mix is a food prepared from the same ingredients and in the same manner prescribed in section 21a-58-15 (g) for ice cream mix, and complies with all the provisions of section 21a-58-15 except that: (a) Its content of milk fat is not less than three and one-quarter per cent. (b) Its content of total milk solids is not less than 13.25 per cent. (c) Caseinates may be added when the content of total milk solids is not less than 13.25 per cent. The name of the product is "milk shake mix."

(Effective July 27, 1984)

Sec. 21a-58-13. Frozen dessert mix regulations and definitions

Frozen dessert mix shall not contain more than fifty thousand standard plate count colonies or more than five coliform organisms per gram based on standard methods for the examination of dairy products as published by American Public Health Association.

(a) **Pasteurization.** The terms "pasteurization," "pasteurized" and similar terms shall be taken to refer to the process of heating every particle of mix to any one of the following

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temperatures and holding at the temperature for the specified time.

155°F. and holding at such temperature for at least thirty minutes.

160°F. and holding at such temperature for at least fifteen minutes.

165°F. and holding at such temperature for at least ten minutes.

170°F. and holding at such temperature for at least five minutes.

175°F. and holding at such temperature for at least twenty-five seconds.

194°F. using the Vacreator process.

200°F. and holding at such temperature for at least three seconds.

210°F. or higher with no holding time required.

Nothing contained in this definition shall be construed as barring such other method or process, or combination of times and temperatures, as may be subsequently approved by the commissioner.

(b) During pasteurization, a competent operator shall be in charge, who shall have passed an examination satisfactory to the commissioner, and shall hold a certificate to operate the pasteurizer, which certificate shall be renewed each year during the month of January. A pasteurizing certificate issued by a state department other than the department of consumer protection will be acceptable.

(c) A recording thermometer shall be provided for each pasteurizer. Each such recording thermometer shall be equipped with a chart perforator, and chart, so used, shall designate the range of 150°F. to 180°F. in 1°F. graduations. Time represented by smallest time scale division shall be not more than ten minutes.

(d) An accurate indicating thermometer shall be inserted in each pasteurizer during the entire heating and holding period of each vat of mix.

(e) All recording thermometer charts shall be preserved for a period of three months for inspection by the commissioner or his authorized agents. No chart shall be used more than one day except with the permission of the commissioner. All charts shall contain the following information: Date of use; number or location of the recorder, if more than one is used; reading of indicating thermometer at some time indicated on the chart during the holding period; amount and kind of pasteurized product, or batch number represented on chart; signature or initials of operator.

(f) **Cooling.** All frozen dessert mix shall be immediately cooled after pasteurization to 45°F. or less, and held at a temperature not to exceed 45°F. until frozen.

(g) **Labeling.** Each frozen dessert mix container shall bear a tag or label containing (1) the standardized name of the mix, (2) the date of pasteurization, (3) the percentage of butter fat and (4) the name and address of the processing plant. Ice milk and fruit sherbet mix tags or labels shall designate artificial coloring by the statement “artificially colored,” “artificial coloring added,” “with added artificial coloring” or “. . . . , an artificial color added,” the blank being filled in with the name of the artificial coloring used. Ice cream mix, frozen custard mix, French ice cream mix, French custard ice cream mix, ice milk mix and fruit sherbet mix labeling shall designate artificial flavoring by the statement “artificially flavored,” “artificial flavoring added,” “with added artificial flavoring” or “. . . . , an

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artificial flavor added,” the blank being filled in with the name of the artificial flavoring used.

(Effective July 27, 1984)

Sec. 21a-58-14. Frozen dessert labeling

(a) Frozen desserts, when in packaged form, shall bear a label containing:

- (1) the standardized name of the product;
- (2) the net weight or volume of contents; and

(3) the name and plant address of the manufacturer. In lieu of such name and address, the name and address of the packer or distributor, together with the Connecticut license number of such manufacturer, or the name and home address of the manufacturer together with the Connecticut license number of such manufacturer.

(b) Where ice milk is served or sold directly from a frozen dessert manufacturing machine or bulk container, a sign shall be conspicuously placed in plain view of all patrons and near the service area, reading “Ice Milk Sold Here.” Such signs shall be of bold type lettering, not less than three inches in height, with such lettering of a contrasting color with that of the sign background.

(Effective July 27, 1984)

Sec. 21a-58-15. Ice cream and frozen custard: identity; label statement

(a) Description

(1) Ice cream is a food produced by freezing, while stirring, a pasteurized mix consisting of one or more of the optional dairy ingredients specified in paragraph (b) of this section, and may contain one or more of the optional caseinates specified in paragraph (c) of this section subject to the conditions hereinafter set forth, and other safe and suitable nonmilk-derived ingredients; and excluding other food fats, except such as are natural components of flavoring ingredients used or added in incidental amounts to accomplish specific functions. Ice cream is sweetened with nutritive carbohydrate sweeteners and may or may not be characterized by the addition of flavoring ingredients.

(2) Ice cream contains not less than 1.6 pounds of total solids to the gallon and weighs not less than 4.5 pounds to the gallon. Ice cream contains not less than 10 per cent milkfat, nor less than 10 per cent nonfat milk solids, except that when it contains milkfat at 1 per cent increments above the 10 per cent minimum, it may contain the following milkfat-to-nonfat milk solids levels:

Per cent milkfat	Minimum per cent non fat milk solids
10	10
11	9
12	8

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Except that when one or more bulky flavors are used, the weights of milkfat and total milk solids are not less than 10 per cent and 20 per cent, respectively, of the remainder obtained by subtracting the weight of the bulky flavors from the weight of the finished food; but in no case is the weight of milkfat or total milk solids less than 8 per cent and 16 per cent, respectively, of the weight of the finished food. Except in the case of frozen custard, ice cream contains less than 1.4 per cent egg yolk solids by weight of the food, exclusive of the weight of any bulky flavoring ingredients used. Frozen custard shall contain 1.4 per cent egg yolk solids by weight of the finished food; provided, however, that when bulky flavors are added the yolk solids content of frozen custard may be reduced in proportion to the amount by weight of the bulky flavors added, but in no case is the content of egg yolk solids in the finished food less than 1.12 per cent. A product containing egg yolk solids in excess of 1.4 per cent, the maximum set forth in this paragraph for ice cream, may be marketed if labeled as specified by paragraph (e) (1) of this section.

(3) When calculating the minimum amount of milkfat and nonfat milk solids required in the finished food, the solids of chocolate or cocoa used shall be considered a bulky flavoring ingredient. In order to make allowance for additional sweetening ingredients needed when certain bulky ingredients are used, the weight of chocolate or cocoa solids used may be multiplied by 2.5; the weight of fruit or nuts used may be multiplied by 1.4; and the weight of partially or wholly dried fruits or fruit juices may be multiplied by appropriate factors to obtain the original weights before drying and this weight may be multiplied by 1.4.

(b) **Optional dairy ingredients.** The optional dairy ingredients referred to in paragraph (a) of this section are: cream, dried cream, plastic cream, (sometimes known as concentrated milk fat), butter, butter oil, milk, concentrated milk, evaporated milk, sweetened condensed milk, superheated condensed milk, dried milk, skim milk, concentrated skim milk, evaporated skim milk, condensed skim milk, superheated condensed skim milk, sweetened condensed skim milk, sweetened condensed part skim milk, nonfat dry milk, sweet cream buttermilk, condensed sweet cream buttermilk, dried sweet cream buttermilk, skim milk that has been concentrated and from which part of the lactose has been removed by crystallization, skim milk in concentrated or dried form which has been modified by treating the concentrated skim milk with calcium hydroxide and disodium phosphate, and whey and those modified whey products (e.g., reduced lactose whey, reduced minerals whey, and whey protein concentrate) that have been determined by FDA to be generally recognized as safe (GRAS) for use in this type of food. Water may be added, or water may be evaporated from the mix. The sweet cream buttermilk and the concentrated sweet cream buttermilk or dried sweet cream buttermilk, when adjusted with water to a total solids content of 8.5 per cent, has a titratable acidity of not more than 0.17 per cent, calculated as lactic acid. The term "milk" as used in this section mean cow's milk. Any whey and modified whey products used contribute, singly or in combination, not more than 25 per cent by weight of the total

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nonfat milk solids content of the finished food. The modified skim milk, when adjusted with water to a total solids content of 9 per cent is substantially free of lactic acid as determined by titration of 0.1N NaOH, and it has a pH value in the range of 8.0 to 8.3.

(c) **Optional caseinates.** The optional caseinates referred to in paragraph (a) of this section which may be added to ice cream mix containing not less than 20 percent total milk solids are: Casein prepared by precipitation with gums, ammonium caseinate, calcium caseinate, potassium caseinate, and sodium caseinate. Caseinate may be added in liquid or dry form, but must be free of excess alkali.

(d) **Methods of analysis.** Fat content shall be determined by the following methods contained in the "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed., (1980). (A.O.A.C. Methods).

(1) Fat content shall be determined by the method: "Fat: Roese-Gottlieb-Method Official Final Action," (A.O.A.C., section 16.287).

(e) **Nomenclature.**

(1) The name of the food is "ice cream"; except that when the egg yolk solids content of the food is in excess of that specified for ice cream by paragraph (a) of this section, the name of the food is "frozen custard" or "french ice cream" or "french custard ice cream."

(2) (i) If the food contains no artificial flavor, the name on the principal display panel or panels of the label shall be accompanied by the common or usual name of the characterizing flavor, e.g., "vanilla" in letters not less than one-half the height of the letters used in the words "ice cream."

(ii) If the food contains both a natural characterizing flavor and an artificial flavor simulating it, and if the natural flavor predominates, the name on the principal display panel or panels of the labels shall be accompanied by the common name of the characterizing flavor, in letters not less than one-half the height of the letters used in the words "ice cream," followed by the word "flavored," in letters not less than one-half the height of the letters in the name of the characterizing flavor, e.g., "vanilla flavored," or "peach flavored," or "vanilla flavored and strawberry flavored."

(iii) If the food contains both a natural characterizing flavor and an artificial flavor simulating it, and if the artificial flavor predominates, or if artificial flavor is used alone, the name on the principal display panel or panels of the label shall be accompanied by the common name of the characterizing flavor in letters not less than one-half the height of the letters used in the words "ice cream," preceded by "artificial" or "artificially flavored," in letters not less than one-half the height of the letters in the name of the characterizing flavor, e.g., "artificial vanilla," or "artificially flavored strawberry" or "artificially flavored vanilla and artificially flavored strawberry."

(3) (i) If the food is subject to the requirements of paragraph (e) 2 (ii) of this section or if it contains any artificial flavor not simulating the characterizing flavor, the label shall also bear the word "artificial flavor added" or "artificial _____ flavor added," the blank being filled in with the common name of the flavor simulated by the artificial flavor in letters of the same size and prominence as the words that precede and

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follow it.

(ii) Wherever the name of the characterizing flavor appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words prescribed by this paragraph shall immediately and conspicuously precede or follow such name, in a size reasonably related to the prominence of the name of the characterizing flavor and in any event the size of the type is not less than 6-point on packages containing less than 1 pint, not less than 8-point on packages containing at least 1 pint but less than one-half gallon, not less than 10-point on packages containing at least one-half gallon but less than 1 gallon, and not less than 12-point on packages containing 1 gallon or over; provided, however, that where the characterizing flavor and a trademark or brand are presented together, other written, printed, or graphic matter that is a part of or is associated with the trademark or brand, may intervene if the required words are in such relationship with the trademark or brand as to be clearly related to the characterizing flavor; and provided further, that if the finished product contains more than one flavor of ice cream subject to the requirements of this paragraph, the statements required by this paragraph need appear only once in each statement of characterizing flavors present in such ice cream, e.g., “vanilla flavored, chocolate and strawberry flavored, artificial flavors added.”

(4) If the food contains both a natural characterizing flavor and an artificial flavor simulating the characterizing flavor, any reference to the natural characterizing flavor shall, except as otherwise authorized by this paragraph, be accompanied by a reference to the artificial flavor, displayed with substantially equal prominence, e.g., “strawberry and artificial strawberry flavor.”

(5) An artificial flavor simulating the characterizing flavor shall be deemed to predominate:

(i) In the case of vanilla beans or vanilla extract used in combination with vanillin if the amount of vanillin used is greater than 1 ounce per unit of vanilla constituent, as defined in 21 CFR 169.3 (c).

(ii) In the case of fruit or fruit juice used in combination with artificial fruit flavor, if the quantity of the fruit or fruit juice used is such that, in relation to the weight of the finished ice cream, the weight of the fruit or fruit juice, as the case may be (including water necessary to reconstitute partially or wholly dried fruits or fruit juices to their original moisture content) is less than 2 per cent in the case of citrus ice cream, 6 per cent in the case of berry or cherry ice cream, and 10 per cent in the case of ice cream prepared with other fruits.

(iii) In the case of nut meats used in combination with artificial nut flavor, if the quantity of nut meats is such that, in relation to the finished ice cream the weight of the nut meats is less than 2 per cent.

(iv) In the case of two or more fruits or fruit juices, or nut meats, or both, used in combination with artificial flavors simulating the natural flavors and dispersed throughout the food, if the quantity of any fruit or fruit juice or nut meat is less than one-half the applicable percentage specified in paragraph (e) (5) (ii) or (iii) of this section. For example, if a combination ice cream contains less than 5 per cent of bananas and less than 1 per cent

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of almonds if would be “artificially flavored banana-almond ice cream.” However, if it contains more than 5 per cent of bananas and more than 1 per cent of almonds it would be “banana-almond flavored ice cream.”

(6) If two or more flavors of ice cream are distinctively combined in one package, e.g., “neapolitan” ice cream, the applicable provisions of this paragraph shall govern each flavor of ice cream comprising the combination.

(f) **Label declaration.** Each of the optional ingredients used shall be declared on the label as required by the applicable sections of 21 CFR 101, except that sources of milkfat or milk solids not fat may be declared in descending order of predominance either by the use of all the terms “milkfat and nonfat milk” when one or any combination of two or more of the ingredients listed in 21 CFR 101.4 (b) (3), (4), (8), and (9) are used or alternatively as permitted in 21 CFR 101.4. Pursuant to section 403(k) of the Federal Food, Drug and Cosmetic Act, artificial color need not be declared in ice cream. Voluntary declaration of such color in ice cream is recommended.

(g) **Ice cream mix.** Ice cream mix is the pasteurized, unfrozen product from which ice cream is manufactured. Where applicable, the ingredient and butterfat standards shall be the same as for ice cream.

(Effective July 27, 1984)

Sec. 21a-58-16. Ice milk: identity; label statement

(a) **Description.** Ice milk is the food prepared from the same ingredients and in the same manner prescribed in Section 21a-58-15 for ice cream and complies with all the provisions of Section 21a-58-15 including the requirements for label statement of optional ingredients, except that:

- (1) Its content of milkfat is more than 2 per cent but not more than 7 per cent.
- (2) Its content of total milk solids is not less than 11 per cent.
- (3) Caseinates may be added when the content of total milk solids is not less than 11 per cent.

(4) The provision for reduction in milkfat and nonfat milk solids content from the addition of bulky flavors in Section 21a-58-15 applies, except that in no case will the milkfat content be less than 2 per cent, nor the nonfat milk solids content be less than 4 per cent. When the milkfat content increases in increments of 1 per cent above the 2 per cent minimum, it may contain the following milkfat-to-nonfat milk solids levels:

Per cent milkfat	Minimum per cent non fat Milk solids
2	9
3	8
4	7
5	6
6	5

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(5) The quantity of food solids per gallon is not less than 1.3 pounds.

(6) When any artificial coloring is used in ice milk, directly or as a component of any other ingredients, the label shall bear the statement “artificially colored,” “artificial coloring added,” “with added artificial color,” or “ _____, an artificial color added,” the blank being filled in with the common or usual name of the artificial color; or in lieu thereof, in case the artificial color is a component of another ingredient, “ _____ artificially colored.”

(7) If both artificial color and artificial flavoring are used, the label statements may be combined.

(b) **Nomenclature.** The name of the food is “ice milk.” Ice milk shall be offered for sale, sold or served only in properly labeled factory-filled containers, if the ice milk or any of its ingredients contain added color or any ingredients added for the purpose of imparting a characterizing flavor, except ice milk may be served and sold at retail from a dispensing freezer.

(c) **Ice milk mix.** Ice milk mix is the pasteurized, unfrozen product from which ice milk is manufactured. Where applicable, the ingredient and butterfat standards shall be the same as for ice milk.

(Effective July 27, 1984)

Sec. 21a-58-17. Sherbet: identity; label statement

(a) **Description**

(1) Sherbet is a food produced by freezing, while stirring, a pasteurized mix consisting of one or more of the optional dairy ingredients specified in paragraph (b) of this section, and may contain one or more of the optional caseinates specified in paragraph (c) of this section subject to the conditions hereinafter set forth, and other safe and suitable nonmilk-derived ingredients; and excluding other food fats, except such as are added in small amounts to accomplish specific functions or are natural components of flavoring ingredients used. Sherbet is sweetened with nutritive carbohydrate sweeteners and is characterized by the addition of one or more of the characterizing fruit ingredients specified in paragraph (d) of this section or one or more of the nonfruit-characterizing ingredients specified in paragraph (e) of this section.

(2) Sherbet weighs not less than 6 pounds to the gallon. The milkfat content is not less than 1 per cent nor more than 2 per cent, the nonfat milk-derived solids content not less than 1 per cent, and the total milk or milk-derived solids content is not less than 2 per cent nor more than 5 per cent by weight of the finished food. Sherbet that is characterized by a fruit ingredient shall have a titratable acidity, calculated as lactic acid, of not less than 0.53 per cent.

(b) **Optional dairy ingredients.** The optional dairy ingredients referred to in paragraph (a) of this section are: Cream, dried cream, plastic cream, (sometimes known as concentrated milk fat), butter, butter oil, milk, concentrated milk, evaporated milk, superheated condensed

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milk, sweetened condensed milk, dried milk, skim milk, concentrated skim milk, evaporated skim milk, condensed skim milk, superheated condensed skim milk, sweetened condensed skim milk, sweetened condensed part skim milk, nonfat dry milk, sweet cream buttermilk, condensed sweet cream buttermilk, dried sweet cream buttermilk, skim milk that has been concentrated and from which part of the lactose has been removed by crystallization, and whey and those modified whey products (e.g., reduced lactose whey, reduced minerals whey, and whey protein concentrate) that have been determined by FDA to be generally recognized as safe (GRAS) for use in this type of food. Water may be added, or water may be evaporated from the mix. The sweet cream buttermilk and the concentrated sweet cream buttermilk or dried sweet cream buttermilk, when adjusted with water to a total solids content of 8.5 per cent, has a titratable acidity of not more than 0.17 per cent, calculated as lactic acid. The term “milk” as used in this section means cow’s milk.

(c) **Optional caseinates.** The optional caseinates referred to in paragraph (a) of this section which may be added to sherbet mix are: Casein prepared by precipitation with gums, ammonium caseinate, calcium caseinate, potassium caseinate, and sodium caseinate. Caseinates may be added in liquid or dry form, but must be free of excess alkali. Such caseinates are not considered to be milk solids.

(d) **Optional fruit characterizing ingredients.** The optional fruit characterizing ingredients referred to in paragraph (a) of this section are any mature fruit or the juice of any mature fruit. The fruit or fruit juice used may be fresh, frozen, canned, concentrated, or partially or wholly dried. The fruit may be thickened with pectin or other optional ingredients. The fruit is prepared by the removal of pits, seeds, skins, and cores, where such removal is usual in preparing that kind of fruit for consumption as fresh fruit. The fruit may be screened, crushed, or otherwise comminuted. It may be acidulated. In the case of concentrated fruit or fruit juices, from which part of the water is removed, substances contributing flavor volatilized during water removal may be condensed and reincorporated in the concentrated fruit or fruit juice. In the case of citrus fruits, the whole fruit, including the peel but excluding the seeds, may be used, and in the case of citrus juice or concentrated citrus juices, cold-pressed citrus oil may be added thereto in an amount not exceeding that which would have been obtained if the whole fruit had been used. The quantity of fruit ingredients used is such that, in relation to the weight of the finished sherbet, the weight of fruit or fruit juice, as the case may be (including water necessary to reconstitute partially or wholly dried fruits or fruit juices to their original moisture content), is not less than 2 per cent in the case of citrus sherbets, 6 per cent in the case of berry sherbets, and 10 per cent in the case of sherbets prepared with other fruits. For the purpose of this section, tomatoes and rhubarb are considered as kinds of fruits.

(e) **Optional nonfruit characterizing ingredients.** The optional nonfruit characterizing ingredients referred to in paragraph (a) of this section include, but are not limited to, the following:

- (1) Ground spice or infusion of coffee or tea.
- (2) Chocolate or cocoa, including sirup.

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(3) Confectionery.

(4) Distilled alcoholic beverage, including liqueurs or wine, in an amount not to exceed that required for flavoring the sherbet.

(5) Any natural or artificial food flavoring (except any having a characteristic fruit or fruit-like flavor).

(f) Nomenclature

(1) The name of each sherbet is as follows:

(i) The name of each fruit sherbet is “_____sherbet,” the blank being filled in with the common name of the fruit or fruits from which the fruit ingredients used are obtained. When the names of two or more fruits are included, such names shall be arranged in order of predominance, if any, by weight of the respective fruit ingredients used.

(ii) The name of each nonfruit sherbet is “_____sherbet,” the blank being filled in with the common or usual name or names of the characterizing flavor or flavors; for example, “peppermint,” except that if the characterizing flavor used is vanilla, the name of the food is “_____sherbet,” the blank being filled in as specified by Section 21a-58-15(e) (2) and (5) (i).

(2) When the optional ingredients, artificial flavoring, or artificial coloring are used in sherbet, they shall be named on the label as follows:

(i) If the flavoring ingredient or ingredients consists exclusively of artificial flavoring, the label designation shall be “artificially flavored.”

(ii) If the flavoring ingredients are a combination of natural and artificial flavors, the label designation shall be “artificial and natural flavoring added.”

(iii) The label shall designate artificial coloring by the statement “artificially colored,” “artificial coloring added,” “with added artificial coloring,” or “_____,” and artificial color added,” the blank being filled in with the name of the artificial coloring used.

(g) Characterizing flavor(s). Wherever there appears on the label any representation as to the characterizing flavor or flavors of the food and such flavor or flavors consist in whole or in part of artificial flavoring, the statement required by paragraph (f) (2) (i) and (ii) of this section, as appropriate, shall immediately and conspicuously precede or follow such representation, without intervening written, printed, or graphic matter (except that the word “sherbet” may intervene) in a size reasonably related to the prominence of the name of the characterizing flavor and in any event the size of the type is not less than 6-point on packages containing less than 1 pint, not less than 8-point on packages containing at least 1 pint but less than one-half gallon, not less than 10-point on packages containing at least one-half gallon but less than 1 gallon, and not less than 12-point on packages containing 1 gallon or over.

(h) Display of statements required by paragraph (f) (2). Except as specified in paragraph (g) of this section, the statements required by paragraph (f) (2) of this section shall be set forth on the principal display panel or panels of the label with such prominence and conspicuousness as to render them likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(i) **Label declaration.** Each of the optional ingredients used shall be declared on the label, as required by the applicable sections of 21 CFR 101.

(Effective July 27, 1984)

Sec. 21a-58-18. Nonfruit sherbet: identity; label statement

(a) **Description.**

(1) Nonfruit sherbet is a food having a characteristic fruit-like flavor but shall not contain any fruit or fruit juice. Nonfruit sherbet is prepared by freezing, while stirring, a pasteurized mix consisting of one or more of the optional dairy ingredients specified in paragraph (b) of this section, and may contain one or more of the optional caseinates specified in paragraph (c) of this section subject to the conditions hereinafter set forth, and any other safe and suitable nonmilk-derived ingredients; and excluding other food fats, except such as are added in small amounts to accomplish specific functions. Nonfruit sherbet is sweetened with nutritive carbohydrate sweeteners and contains characteristic fruit-like flavor.

(2) Sherbet weighs not less than 6 pounds to the gallon. The milkfat content is not less than 1 per cent nor more than 2 per cent, the nonfat milk-derived solids content not less than 1 per cent, and the total milk or milk-derived solids content is not less than 2 per cent nor more than 5 per cent by weight of the finished food.

(b) **Optional dairy ingredients.** The optional dairy ingredients referred to in paragraph (a) of this section are: Cream, dried cream, plastic cream (sometimes known as concentrated milk fat), butter, butter oil, milk, concentrated milk, evaporated milk, superheated condensed milk, sweetened condensed milk, dried milk, skim milk, concentrated skim milk, evaporated skim milk, condensed skim milk, superheated condensed skim milk, sweetened condensed skim milk, sweetened condensed part skim milk, nonfat dry milk, sweet cream buttermilk, condensed sweet cream buttermilk, dried sweet cream buttermilk, skim milk that has been concentrated and from which part of the lactose has been removed by crystallization, and whey and those modified whey products (e.g., reduced lactose whey, reduced minerals whey, and whey prin concentrate) that have been determined by FDA to be generally recognized as safe (GRAS) for use in this type of food. Water may be added, or water may be evaporated from the mix. The sweet cream buttermilk and the concentrated sweet cream buttermilk or dried sweet cream buttermilk, when adjusted with water to a total solids content of 8.5 per cent, has a titratable acidity of not more than 0.17 per cent, calculated as lactic acid. The term “milk” as used in this section means cow’s milk.

(c) **Optional caseinates.** The optional caseinates referred to in paragraph (a) of this section that may be added to nonfruit sherbet are: Casein prepared by precipitation with gums, ammonium caseinate, calcium caseinate, potassium caseinate, and sodium caseinate. Caseinates may be added in liquid or dry form, but must be free of excess alkali. Such caseinates are not considered to be milk solids.

(d) **Nomenclature.** The name of the food is “nonfruit sherbet.”

(e) In addition to all other required information, the label shall:

(1) Contain a complete list of ingredients, in accordance with the provisions of 21 CFR

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(2) Comply with the provisions of 21 CFR 101.22.

(3) Contain the following statement “Imitation _____ sherbet.” The blank to be filled in by the characterizing flavor used. The letters in the word imitation shall be the same size, type and color and on the same contrasting background as the name of the characterizing flavor and the word sherbet.

(4) The statement required in paragraph (3) of this subsection shall be followed immediately by the words “contains no fruit or fruit juice” in letters at least half the size of those used in statement (3) above.

(5) When a sign is used at the point of purchase to advertise nonfruit sherbet, it shall contain the same information as required in paragraphs (3) and (4) of this subsection.

(6) When nonfruit sherbet is sold other than in properly labeled factory-filled containers, a sign must be conspicuously displayed on the sale premises or vehicle where it can be clearly read by customers under normal conditions of purchase, stating the information required in paragraphs (3) and (4) above. The letters on such sign shall be bold face capitals at least three inches in height and in contrasting color to the background.

(7) The sign required as per paragraph (6) above need not be used if each customer is provided with a menu stating the information required by paragraph (3) and (4) above in bold face capitals as large as those used in listing most food items.

(Effective July 27, 1984)

Sec. 21a-58-19. Water ices: identity, label statement

(a) **Description.** Water ices are the foods each of which is prepared from the same ingredients and in the same manner prescribed in Section 21a-58-17 for sherbet, except that the mix need not be pasteurized, and complies with all the provisions of Section 21a-58-17 (including the requirements for label statement of optional ingredients) except that no milk or milk-derived ingredient and no egg ingredient, other than egg white, is used.

(b) **Nomenclature.** The name of the food is “_____ ice,” the blank being filled in, in the manner as specified in Section 21a-58-17 (f) (1) (i) and (ii) as appropriate.

(Effective July 27, 1984)

Sec. 21a-58-20. Nonfruit water ices: identity; label statement

(a) **Description.** Nonfruit water ice is an ice having a characteristic fruit-like flavor, but shall not contain any fruit or fruit juice. Nonfruit water ice is prepared, while stirring, a mix composed of:

- (1) Characteristic fruit-like flavors.
- (2) One or more nutritive sweeteners.
- (3) Any other safe and suitable ingredient approved by the Department.

The finished nonfruit water ice weighs not less than six pounds per gallon.

(b) In addition to all other required information, the label shall:

- (1) Contain a complete list of ingredients, in accordance with the provisions of 21 CFR

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(2) Comply with the provisions of 21 CFR 101.22

(3) Contain the following statement “Imitation _____ water ice,” the blank to be filled in by the characterizing flavor used. The letters in the word imitation shall be the same size, type and color and on the same contrasting background as the name of the characterizing flavor and the word water ice.

(4) The statement required in paragraph (3) of this subsection shall be followed immediately by the words “contains no fruit or fruit juice” in letters at least half the size of those used in statement (3) above.

(5) When a sign is used at the point of purchase to advertise nonfruit water ice it shall contain the same information as required in paragraphs (3) and (4) of this subsection.

(6) When nonfruit water ice is sold other than in properly labeled factory-filled containers, a sign must be conspicuously displayed on the sale premises or vehicle where it can be clearly read by customers under normal conditions of purchase, stating the information required in paragraph (3) and (4) above. The letters on such sign shall be bold face capitals at least three inches in height and in contrasting color to the background.

(7) The sign required as per paragraph (6) above need not be used if each customer is provided with a menu stating the information required by paragraph (3) and (4) above in bold face capitals as large as those used in listing most food items.

(Effective July 27, 1984)

Sec. 21a-58-21. Mellorine: identity; label statement

(a) Description.

(1) Mellorine is a food produced by freezing, while stirring, a pasteurized mix consisting of safe and suitable ingredients including, but not limited to, milk-derived nonfat solids and animal or vegetable fat, or both, only part of which may be milkfat. Mellorine is sweetened with nutritive carbohydrate sweetener and is characterized by the addition of flavoring ingredients.

(2) Mellorine contains not less than 1.6 pounds of total solids to the gallon, and weighs not less than 4.5 pounds to the gallon. Mellorine contains not less than 6 per cent fat and 2.7 per cent protein having a protein efficiency ratio (PER) not less than that of whole milk protein (108 per cent of casein) by weight of the food, exclusive of the weight of any bulky flavoring ingredients used. In no case shall the fat content of the finished food be less than 4.8 per cent or the protein content be less than 2.2 per cent. The protein to meet the minimum protein requirements shall be provided by milk solids not fat, and/or other milk-derived ingredients.

(3) When calculating the minimum amount of milkfat and protein required in the finished food, the solids of chocolate or cocoa used shall be considered a bulky flavoring ingredient. In order to make allowance for additional sweetening ingredients needed when certain bulky ingredients are used, the weight of chocolate or cocoa solids used may be multiplied by 2.5; the weight of fruit or nuts used may be multiplied by 1.4; and the weight of partially or

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wholly dried fruits or fruit juices may be multiplied by appropriate factors to obtain the original weights before drying and this weight may be multiplied by 1.4.

(b) **Fortification.** Vitamin A is present in a quantity which will ensure that 40 international units (IU) are available for each gram of fat in mellorine, within limits of good manufacturing practice.

(c) **Methods of analysis.** Fat and protein content, and the PER shall be determined by the following methods contained in the “Official Methods of Analysis of the Association of Official Analytical Chemists,” 13th Ed., (1980) (A.O.A.C. Methods).

(1) Fat content shall be determined by the method: “Fat, Roese-Gottlieb Method-Official Final Action,” (A.O.A.C., section 16.287).

(2) Protein content shall be determined by one of the following methods: “Nitrogen-Official Final Action,” Kjeldahl Method, section 16.285, or Dye Binding Method, section 16.286.

(3) PER shall be determined by the method: Biological Evaluation of Protein Quality-Official Final Action,” sections 43.212–43.216.

(d) **Nomenclature.** The name of the food is “mellorine.” The name of the food on the label shall be accompanied by a declaration indicating the presence of characterizing flavoring in the same manner as is specified in Section 21a-58-15(e).

(e) **Label declaration.** The common or usual name of each of the ingredients used shall be declared on the label in accordance with section 21 CFR 101.4 except that sources of milkfat or milk solids not fat may be declared, in descending order or predominance, either by the use of the terms “milkfat, and nonfat milk” when one or any combination of two or more ingredients listed in 21 CFR 101.4 (b) (3), (4), (8) and (9) are used, or alternatively as permitted in 21 CFR 101.4. Mellorine shall be sold, held, offered for sale by any manufacturer, wholesaler, retailer, or any other seller only in factory-filled containers not larger than one-half gallon.

(Effective July 27, 1984)

Sec. 21a-58-22. Goats milk ice cream and goats milk ice milk: identity; label statement

(a) **Description.** Goats milk ice cream is a food prepared in the same manner and from the same ingredients permitted for ice cream in Section 21a-58-15 and shall comply with all the provisions of Section 21a-58-15 including provisions for label statements of optional ingredients except that all milkfat and nonfat milk solids shall be from goats milk. No milkfat or nonfat milk solids from any source other than goats milk will be permitted in goats milk ice cream. On the label, in the name of the food, the letters in the words “Goats Milk” shall be the same size, type, and color, and on the same contrasting background as the letters in the words “Ice Cream.”

(b) Goats milk ice milk is a food prepared in the same manner and from the same ingredients permitted for ice milk in Section 21a-58-16 and shall comply with all the provisions of Section 21a-58-16 including provisions for label statements of optional

ingredients except that all milkfat and nonfat milk solids shall be from goats milk. No milk fat or nonfat milk solids from any source other than goats milk will be permitted in goats milk ice milk. On the label, in the name of the food, the letters in the words “Goats Milk” shall be the same size, type, and color, and on the same contrasting background as the letters in the words “Ice Milk.”

(Effective July 27, 1984)

Sec. 21a-58-23. Frozen yogurt: identity; label statement

(a) **Description.** Frozen yogurt is the food which is prepared by freezing, while stirring, a pasteurized mix consisting of the ingredients permitted for ice cream in Section 21a-58-15. Such ingredients are cultured after pasteurization by one or more strains of *Lactobacillus bulgaricus* and *Streptococcus thermophilus*, provided, however, fruit, nuts, or other flavoring materials may be added before or after the mix is pasteurized and cultured. The standard plate count requirement for frozen desserts shall apply to the mix prior to culturing. Frozen yogurt, exclusive of any flavoring, contains not less than 3.25 per cent milkfat, not less than 8.25 per cent milk solids not fat and has a titratable acidity of not less than 0.5 per cent expressed as lactic acid. This characteristic acidity is developed as a result of the bacterial activity and no heat or bacteriostatic treatment, other than refrigeration, which results in destruction or partial destruction of the organisms, shall be applied to the product after such culturing. The finished yogurt shall weigh not less than five pounds per gallon.

(b) The name of the food is “frozen yogurt.”

(c) In addition to all other required information, the label shall contain a complete list of ingredients, in accordance with the provisions of 21 CFR 101.4, and comply with the provisions of subdivisions (h) & (i) of 21 CFR 101.22. On the label of frozen yogurt the strains of bacteria may be collectively referred to as yogurt culture.

(Effective July 27, 1984)

Sec. 21a-58-24. Frozen lowfat or lowfat frozen yogurt: identity; label statement

(a) **Description.** Frozen lowfat yogurt or lowfat frozen yogurt is the food which is prepared by freezing, while stirring, a pasteurized mix consisting of the ingredients permitted for ice cream in Section 21a-58-15. Such ingredients are cultured after pasteurization by one or more strains of *Lactobacillus bulgaricus* and *Streptococcus thermophilus*, provided, however, fruit, nuts, or other flavoring materials may be added before or after the mix is pasteurized and cultured. The standard plate count requirement for frozen desserts shall apply only to the mix prior to culturing. The food, exclusive of any flavoring, contains not less than 0.5 per cent nor more than 2 per cent milkfat and not less than 8.25 per cent milk solids not fat, and has a titratable acidity of not less than 0.5 per cent, expressed as lactic acid. This characteristic acidity is developed as a result of the bacterial activity and no heat or bacteriostatic treatment, other than refrigeration, which results in destruction or partial destruction of the organisms, shall be applied to the product after such culturing. The finished food shall weigh not less than five pounds per gallon.

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(b) The name of the food is “frozen lowfat yogurt” or “lowfat frozen yogurt.”

(c) The label on a package of this food, in addition to all other required information, shall:

(1) Contain a complete list of ingredients, in accordance with the provisions of 21 CFR 101.4.

(2) Contain nutrition information as required by 21 CFR 101.9

(3) Comply with the provisions of subdivisions (h) & (i) of 21 CFR 101.22.

On the label, the strains of bacteria may be collectively referred to as yogurt culture.

(Effective July 27, 1984)

Sec. 21a-58-25. Frozen nonfat yogurt or nonfat frozen yogurt: identity; label statement

(a) **Description.** Frozen nonfat yogurt or nonfat frozen yogurt is the food which is prepared by freezing, while stirring, a pasteurized mix consisting of the ingredients permitted for ice cream in Section 21a-58-15. Such ingredients are cultured after pasteurization by one or more strains of *Lactobacillus bulgaricus* and *Streptococcus thermophilus*, provided, however, fruit, nuts or other flavoring materials may be added before or after the mix is pasteurized and cultured. The standard plate count requirement for frozen desserts shall apply only to the mix prior to culturing. The food, exclusive of any flavoring, contains less than 0.5 per cent milkfat, not less than 8.25 per cent milk solids not fat and has a titratable acidity of not less than 0.5 per cent expressed as lactic acid. This characteristic acidity is developed as a result of the bacterial activity and no heat or bacteriostatic treatment, other than refrigeration, which results in partial destruction of the organisms, shall be applied to the product after such culturing. The finished food shall weigh not less than five pounds per gallon.

(b) The name of the food is “frozen nonfat yogurt” or “nonfat frozen yogurt.”

(c) The label on a package of this food, in addition to all other information, shall:

(1) Contain a complete list of ingredients, in accordance with the provisions of 21 CFR 101.4.

(2) Contain nutrition information as required by 21 CFR 101.9.

(3) Comply with the provisions of subdivisions (h) & (i) of 21 CFR 101.22.

On the label, the strains of bacteria may be collectively referred to as yogurt culture.

(Effective July 27, 1984)

Sec. 21a-58-26. Quiescently frozen confection: identity; label statement

(a) **Description.** Quiescently frozen confection means the frozen product made from sweetening agents, harmless natural or artificial flavoring, water, and it may contain milk solids, harmless coloring, organic acids, and any safe and suitable functional ingredient approved by the Department. The finished product shall contain not less than 17 per cent by weight of total food solids.

(b) The name of the food is “quiescently frozen confection.” In the manufacture of this

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product, freezing has not been accomplished by stirring or agitation. In the production of this quiescently frozen confection, no processing or mixing prior to quiescent freezing shall be used that develops in the finished confection mix any physical expansion in excess of 10 per cent.

(c) This confection must be manufactured in the form of servings, individually packaged, bagged or otherwise wrapped, properly labeled and purveyed to the consumer in its original factory-filled package. The individually wrapped confection need not be labeled if it is contained in a multiple package which is properly labeled and is purveyed unopened to the consumer. In addition to all other required information, the label shall contain a complete list of ingredients in accordance with the provisions of 21 CFR 101.4, and comply with the provisions of subdivisions (h) & (i) of 21 CFR 101.22.

(Effective July 27, 1984)

Sec. 21a-58-27. Quiescently frozen dairy confection: identity; label statement

(a) **Description.** Quiescently frozen dairy confection means the frozen product made from milk products, sweetening agents, harmless natural or artificial flavoring, water and it may contain harmless coloring, and any safe and suitable functional ingredient approved by the Department. The finished product contains not less than 13 per cent by weight of total milk solids, not less than 33 per cent by weight of total food solids.

(b) The name of the food is “quiescently frozen dairy confection.” In the manufacture of this product, freezing has not been accompanied by stirring or agitation. In the production of this quiescently frozen dairy confection, no processing or mixing prior to quiescent freezing shall be used that develops in the finished confection mix any physical expansion in excess of 10 per cent.

(c) This confection must be manufactured in the form of servings, individually packaged, bagged or otherwise wrapped, properly labeled and purveyed to the consumer in its original factory-filled package. The individually wrapped confection need not be labeled if it is contained in a multiple package which is properly labeled and is purveyed unopened to the consumer. In addition to all other required information, the label shall contain a complete list of ingredients in accordance with the provisions of 21 CFR 101.4, and comply with the provisions of subdivisions (h) & (i) of 21 CFR 101.22.

(Effective July 27, 1984)

Sec. 21a-58-28. Frozen dietary dairy dessert: identity; label statement

(a) **Description.** Frozen dietary dairy dessert means a frozen dessert prepared for persons who wish to restrict their intake of ordinary sweetening ingredients. It is produced by freezing, while stirring, a pasteurized mix consisting of the ingredients permitted for ice cream in Section 21a-58-15. The minimum fat content shall be 3 per cent, it shall contain no sugars other than those naturally present in the milk solids or flavoring agents which have been added thereto, and it may contain edible carbohydrates other than sugars. The edible carbohydrates must be approved by the Department.

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(b) The name of the food is “frozen dietary dairy dessert.”

(c) The label on a package of frozen dietary dairy dessert in addition to other required information shall:

(1) Contain a complete list of ingredients in accordance with the provisions of 21 CFR 101.4;

(2) Contain a statement as follows:

“Diabetics: This product may be useful in your diet on the advice of a physician. This food is not a reduced calorie food.”

(3) Immediately preceding or following the name of the product contain a statement as follows: “Contains _____% milkfat,” the blank to be filled in with the percentage of milkfat in the product;

(4) Contain nutrition information as required by 21 CFR 101.9; and

(5) Comply with the provisions of subdivisions (h) & (i) of CFR 101.22.

(d) The product shall not be sold in any manner other than in sealed or unbroken packages or containers.

(Effective July 27, 1984)

Sec. 21a-58-29. Dietary frozen dessert or lowfat frozen dairy dessert: identity; label statement

(a) **Description.** Dietary frozen dessert or lowfat frozen dairy dessert is the food prepared by freezing, while stirring, a pasteurized mix consisting of the ingredients permitted for ice cream in Section 21a-58-15. The finished product contains less than 2 per cent by weight of ether extractable fat; its content of total milk solids consisting of ingredients listed in paragraph (b) of Section 21a-58-15 is not less than 7 per cent by weight. The product weighs not less than 4.5 pounds per gallon and the quantity of food solids per gallon is not less than 1.1 pounds nor more than 1.9 pounds, exclusive of any micro-crystalline cellulose used as an ingredient.

(b) One or more vitamins and/or minerals listed in 21 CFR 101.9 (c) (7) (iv) may be added to the product. If vitamins and/or minerals are added, the name of the food on the principal display panel and each alternate principal display panel shall be immediately preceded or followed by the word “fortified” in the same style and at least one-half the size of the type used for the name “dietary frozen dessert” or “lowfat frozen dairy dessert” and on the same contrasting background. If vitamins and/or minerals are added, then each four fluid ounce serving of finished product shall provide no less than 8 per cent nor more than 20 per cent of the U.S. Recommended Daily Allowance of such vitamins and/or minerals.

(c) The name of the food is “dietary frozen dessert” or “lowfat frozen dairy dessert.”

(d) The label on dietary frozen dessert or lowfat frozen dairy dessert, in addition to all other required information, shall:

(1) Contain a complete list of ingredients, in accordance with the provisions of 21 CFR 101.4;

(2) Contain nutrition information as required by 21 CFR 101.9; and

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(3) Comply with the provisions of subdivisions (h) & (i) of 21 CFR 101.22.

(e) When the food is hand dipped or sold from a dispensing freezer, hand out materials shall be made available to consumers which provides the information required above by Section 21a-58-29(d)(1) and (2), and signs shall be prominently displayed of such size and location as to be easily seen by customers. The letters on such sign shall be bold face capitals at least three inches in height and in contrasting color to the background.

(Effective July 27, 1984)

Sec. 21a-58-30. Manufactured desserts mix: identity; label statement

(a) **Description.** “Manufactured desserts mix,” whipped cream confection, or bisque tortoni means a frozen dessert made with milk products, sweetening agents, flavoring agents, with or without harmless coloring or any other safe and suitable ingredients approved by the Commissioner. The product must contain not less than 18 per cent by weight of milk fat, and not more than 12 per cent of milk solids not fat, and may be packaged with harmless gas causing it to fluff upon ejection from the package or container.

(b) In addition to all other required information, the label shall contain a complete list of ingredients in accordance with the provisions of 21 CFR 101.4.

(Effective July 27, 1984)

Sec. 21a-58-31. Freezer made shake—freezer made milk shake: identity; label statement

(a) **Description.** Freezer made milk shake means a pure, clean, wholesome semi-viscous drink prepared by stirring, while freezing, a pasteurized mix consisting of the ingredients prescribed for ice milk in Section 21a-58-16 of these regulations except that:

(1) It shall contain not less than 3.25 per cent and not more than 6 per cent milk fat.

(2) Its content of milk solids not fat shall not be less than 10 per cent.

(b) Other freezer made shakes including jumbo shake, thick shake, T.V. shake, or any coined or trade name containing the word “shake” shall meet the requirements of paragraph (a), except that the minimum per cent of milk fat may be less than 3.25 per cent.

(c) “Shakes” not meeting the requirement for “milk shakes” shall not be advertised, sold or served as milk shakes.

(d) When any freezer made milk shake or other freezer made shake purports to be or is represented for any special dietary use by man, it shall be sold only in a container with an ingredient listing in accordance with the provisions of 21 CFR 101.4, and nutrition information as required by 21 CFR 101.9.

(Effective July 27, 1984)

Sec. 21a-58-32. Parevine: identity; label statement

(a) **Description.** Parevine is the food which is prepared by freezing, while stirring, a pasteurized mix composed of:

(1) One or more edible vegetable oils or fats.

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- (2) Protein and carbohydrate food ingredients from other than milk or meat sources.
 - (3) Nutritive sweeteners other than lactose.
 - (4) Characterizing ingredients except any containing meat or milk.
 - (5) Any other safe and suitable ingredient which is not milk or meat or a product or derivative of milk or meat. This product shall not contain any milk, milk product, meat or meat products or any of their derivatives of any kind.
 - (b) Its fat content shall not be less than 10 per cent, except that when bulky optional characterizing ingredients are used, the fat content may be reduced, as a result of the addition of such ingredients, but shall in no case be less than 8 per cent.
 - (c) Its content of food solids shall not be less than 1.3 pounds per gallon of the finished product.
 - (d) The name of the food is “parevine.”
 - (e) Parevine shall be sold, held, offered for sale by any manufacturer, wholesaler, retailer, or any other seller only in properly labeled factory-filled containers, except parevine may be served other than in a properly labeled factory-filled container if a sign is conspicuously displayed where it can easily be read under normal conditions of purchase, stating “PAREVINE SOLD HERE.” Letters on such sign shall be bold face capitals at least three inches in height and in contrasting color to the background. No such sign need be displayed if each customer is provided with a menu on which there is stated “PAREVINE SERVED HERE” in bold face capitals as large as those used in listing most food items.
 - (f) The label on packages of parevine shall, in addition to all other required information, include a complete list of all ingredients in accordance with the provisions of 21 CFR 101.4.
- (Effective July 27, 1984)

Sec. 21a-58-33. Lowfat parevine: identity, label statement

- (a) **Description.** Lowfat parevine is the food which meets all of the provisions of Section 21a-58-32, except that the fat content shall not be more than 6 per cent.
- (b) The name of the product is “lowfat parevine.”
- (c) The sign required by Section 21a-58-32(e) shall read “LOWFAT PAREVINE SOLD HERE.”

(Effective July 27, 1984)

Sec. 21a-58-34. Lo-mel: identity; label statement

- (a) **Description.** “Lo-mel” means a pure, clean, wholesome semi-viscous drink prepared by stirring, while freezing, in a dispensing freezer a pasteurized mix composed of edible fats or oils other than milk fat, milk solids not fat, water, optional sweetening ingredients as approved by the commissioner, with or without egg products, with or without harmless flavoring, with or without harmless coloring, and with or without stabilizer or emulsifier as approved by the commissioner. It shall contain not more than 6 per cent edible fats or oils. It shall contain not less than 10 per cent milk solids not fat. It may contain any other safe and suitable ingredients approved by the commissioner. It shall contain not more than one-

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half per cent by weight of stabilizer and not more than one-fifth of one per cent of emulsifier. It may contain optional sweetening ingredients and any other safe and suitable ingredients approved by the department.

(b) Lo-mel may only be served or sold directly from a dispensing freezer and may not be sold hard frozen.

(c) When lo-mel is sold from a dispensing freezer a sign must be prominently and conspicuously displayed which shall read "LO-MEL SERVED HERE," in bold face capitals at least three inches in height and in contrasting color to the background. Such sign shall include a list of all ingredients in a manner acceptable to the department, provided, however, that the name of the edible fats or oils used, other than milk fat, must be specified. The letters on such sign shall be of sufficient size to be read by consumers under normal conditions of purchase. No such list of ingredients need be included on the sign if the list of ingredients is printed on the side of the container in which the product is served to the customer.

(d) When any lo-mel purports to be or is represented for any special dietary use by man, it shall be sold only in a container with an ingredient listing in accordance with all applicable provision of the Regulations of the Federal Food and Drug Administration.

(Effective July 27, 1984)

Sec. 21a-58-35. Lactose reduced ice cream; identity; label statement

(a) **Description.** Lactose reduced ice cream is the product resulting from the treatment of ice cream, as defined in Section 21a-58-15, by the addition of safe and suitable enzyme(s) to convert sufficient amounts of lactose to glucose and galactose so that the remaining lactose is 30 per cent or less than the lactose in ice cream.

(b) The name of the food is "lactose reduced ice cream."

(c) The label on lactose reduced ice cream, in addition to all other required information, shall contain a complete list of ingredients in accordance with the provisions of 21 CFR 101.4, and contain nutrition information as required by 21 CFR 101.9.

(d) Wherever the name of the food appears on the container, the words "lactose reduced" shall be in the same type, style and size and in the same color and contrasting background as the words "ice cream."

(Effective July 27, 1984)

Sec. 21a-58-36. Lactose reduced ice milk: identity; label statement

(a) **Description.** Lactose reduced ice milk is the product resulting from the treatment of ice milk, as defined in Section 21a-58-16, by the addition of safe and suitable enzyme(s) to convert sufficient amounts of lactose to glucose and galactose, so that the remaining lactose is 30 per cent or less than lactose in ice milk.

(b) The name of the food is "lactose reduced ice milk."

(c) The label on lactose reduced ice milk, in addition to all other required information, shall contain a complete list of ingredients in accordance with the provisions of 21 CFR

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101.4, and contain nutrition information as required by 21 CFR 101.9.

(d) Wherever the name of the food appears on the container, the words “lactose reduced” shall be in the same type, style and size and in the same color and contrasting background as the words “ice milk.”

(Effective July 27, 1984)

Sec. 21a-58-37. Frozen pudding: identity; label statement

(a) **Description.** Frozen pudding is a product made from a pasteurized mix, intended to be eaten in the frozen state. The mix may be composed of:

- (1) Milk and milk products.
- (2) Modified or unmodified food starch.
- (3) Sweetening agents.
- (4) Harmless natural and/or artificial flavoring.
- (5) Harmless natural and/or artificial color.
- (6) Any other safe or suitable functional ingredient.

(b) The finished product shall contain:

- (1) Not less than 5 per cent by weight milk solids not fat.
- (2) Not less than 25 per cent total food solids.

(c) The weight of the finished product shall be not less than 4.5 pounds per gallon.

(d) If not frozen promptly after pasteurization, the finished product shall be cooled to 50°F or lower and maintained thereat, or the finished product shall be cooled and maintained under conditions to assure suitability for consumption.

(e) The name of the food is “frozen pudding.”

(f) The package label shall, in addition to all other required information, include a complete list of all ingredients in accordance with the provisions of 21 CFR 101.4 and 21 CFR 101.22.

(Effective July 27, 1984)

Sec. 21a-58-38. Exceptions to pasteurization of frozen dairy dessert mix

(a) Frozen desserts with additives that meet the requirements of the latest revision of the Pasteurized Milk Ordinance (PMO), as adopted by reference in section 22-133-115 of the Regulations of Connecticut State Agencies, shall be permitted, provided that:

(1) Such products shall be made with milk and milk products that have been pasteurized and have been obtained from a source operating in compliance with the the PMO, and all added ingredients shall meet the requirements of the PMO;

(2) Pasteurized milk and milk products used in production shall only come from single-use packaging, and said products shall be completely used in a single day’s production; and

(3) Added powdered ingredients, other than flavorings, shall only come from aseptically packaged single-batch containers.

(b) Frozen desserts that are produced from ingredients in accordance with subsection (a) of this section are exempt from the need to pasteurize the frozen dessert mix prior to

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flavoring and freezing, provided that the production process and resulting mix complies with the following specifications:

(1) The frozen dessert shall be manufactured to be served directly to the consumer in single serving containers designed for consumption at the time of delivery, such as being scooped or spooned into cones or cups for immediate consumption;

(2) The frozen dessert shall be made with pasteurized dairy and pasteurized egg products obtained from single-use packaging, which products shall be completely used in a single day's production;

(3) Sweeteners and flavorings approved for use for the particular type of frozen dessert shall be stored in a manner that would prevent contamination, and may be blended into the mix;

(4) In addition to sweeteners and flavorings, other ingredients allowed for frozen desserts as specified in this section may be added provided they are packaged in aseptic packaging and are used completely within a single day's production;

(5) Make sheets shall be maintained for each base batch with a tracking system that allows easy traceability of all the ingredients used in each batch;

(6) Dairy, egg and other perishable ingredients, and the prepared mix, shall be held at or below 38° F at all times. If the mix is to be "heat treated," the target temperature shall be reached not later than sixty (60) minutes after starting the heating process, and after heat treatment is concluded, it shall not take longer than sixty (60) minutes for the mix to be cooled to 38° F or below;

(7) The mix shall be frozen within one hundred forty four (144) hours of preparation;

(8) Unfrozen mix shall be date marked in a manner consistent with the requirements set forth in the Uniform Open Dating Regulation, as amended from time to time by the National Conference on Weights and Measures and published in the National Institute of Standards and Technology Handbook 130, or subsequent corresponding handbook of the United States Department of Commerce. The dates of preparation and disposal shall be indicated on any prepared product; and

(9) All other applicable regulations shall be complied with.

(Effective April 2, 2015)

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Subject

Frozen Food Regulations

Inclusive Sections

§§ 21a-61-1—21a-61-8

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Frozen Food Regulations

Sec. 21a-61-1. Definitions

The following definitions shall apply in the interpretation of sections 21a-61-1 to 21a-61-8 inclusive:

(1) “Accessible” means easily exposed for cleaning and inspection with the use of simple tools, such as those normally used by maintenance personnel.

(2) “Air temperature” means the equilibrated temperature of the air environment in question.

(3) “Break-up room” means any area, or space within a warehouse, used for the purpose of organizing cased frozen food into lots for individual consignment on route delivery.

(4) “Carrier” means any person, firm or corporation, operating or offering to operate a vehicle for the purpose of transporting frozen food.

(5) “Display case” means any case, cabinet or other facility used for displaying frozen food for sale.

(6) “Food product zone” means those surfaces with which food is normally in contact and those surfaces with which food may come in contact during processing, conveying, holding, refrigeration and packing, and which may drain onto product contact surfaces or into the product.

(7) “Freezing cycle” means lowering of the internal product temperature of a food product to a temperature of 0°F. or lower.

(8) “Frozen food” means any article used for food or drink for man or other animals (a) which is processed; (b) which is packaged and preserved by freezing in accordance with good commercial practices, and (c) which is intended for sale in the frozen state.

(9) “Internal product temperature” means the equilibrated product temperature of frozen food.

(10) “Operator” means any person, firm or corporation, operating or maintaining a frozen food plant or warehouse for the purpose of commercially preparing or storing frozen food.

(11) “Readily (or easily) accessible” means easily exposed, without the use of tools, for cleaning and inspection.

(12) “Readily removable” means that a component part shall be capable of being separated from the principal part without the use of tools.

(13) “Ready to eat frozen food” means a frozen food product which has been factory processed to the point at which it is ready for use as a food, and may or may not require further heating before use.

(14) “Removable” means that a component part shall be capable of being separated from the principal part with the use of simple tools such as those normally used by maintenance personnel.

(15) “Retail outlet” means any building, room or parts thereof where the sale of frozen food to the public is conducted.

(16) “Route delivery” means the transportation of frozen food with frequent stops for partial unloading.

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(17) “Sale” means any and every transaction including the dispensing, giving, delivering, serving, exposing or storing or any other possessing of frozen food wherein frozen food is subject to transfer to another person.

(18) “Storage room or facility” means any area or space, within a warehouse, used for the purpose of storing frozen food.

(19) “Transportation” means the physical movement, or the acceptance for physical movement, of frozen food by a carrier.

(20) “Vehicle” means any van, truck, trailer, automobile, wagon, ship, barge, freight car, airplane or other means for transporting frozen food.

(21) “Warehouse” means any structure, room or part thereof used for the purpose of storing commercially manufactured frozen food.

(Effective July 27, 1984)

Sec. 21a-61-2. Frozen food: General

(a) **General.** (1) All frozen food shall be held at an air temperature of 0°F. or lower except for defrost cycles, loading and unloading, or other temporary conditions beyond the immediate control of the person or company under whose care or supervision the frozen food is held; provided only those frozen foods destined for repackaging in smaller units may be defrosted for such purposes in accordance with good sanitary precautions. (2) The internal product temperature of frozen food shall be maintained at 0°F. or lower except when the product is subjected to the above-mentioned conditions, in which case the internal product temperature shall not exceed 10°F. and such product shall be returned to 0°F. as quickly as possible. (3) Internal product temperature for any case of frozen food shall be determined in accordance with the following procedure: Only when an accurate determination of internal product temperature fails without sacrifice of packaged frozen food shall representative packages or units be opened to allow for inserting the sensing element for temperature measurement to the approximate center of the packages in question. (4) Internal product temperature of consumer packages of frozen food shall be determined in accordance with the following procedure: (A) Open the top of the case and remove two corner packages; (B) with an ice pick or similar tool, punch a hole in the case from the inside. Do not use the stem of the thermometer; (C) this hole is positioned so that, when the thermometer stem is inserted from the outside, it fits snugly between packages; (D) insert the thermometer stem about three inches. Replace the two packages. Close the case and place a couple of other cases on top to assure good contact on the sensing portion of the thermometer stem; (E) after five minutes, read the temperature. (5) Thermometers or other temperature measuring devices shall have an accuracy of + or – 2°F.

(b) **Exception.** Sections 21a-61-1 to 21a-61-8, inclusive, shall not apply or be deemed to apply to articles subject to the Frozen Desserts Ordinance and Code, recommended by the U.S. Public Health Service—May, 1940.

Sec. 21a-61-3. Construction and layout of frozen food plants

(a) **Coverage.** (1) This section covers in general the location, construction and layout of

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frozen food preparation plants, including construction and design requirements to promote cleaning and sanitary maintenance. (2) The provisions of this section shall be applicable only to those establishments initiating operations subsequent to the first inspection based upon the requirements of these regulations, provided plants in existence on April 10, 1962, shall be subject to the provisions of these regulations when the plant facilities are remodeled or rebuilt subsequent to the adoption of these regulations, or when such plant or plant facility constitutes an immediate health hazard.

(b) **Location.** (1) Food processing plants shall be located in areas reasonably free from objectionable odors, smoke, flying ash and dust or other contamination. (2) Adequate, dust-proof accessways for all vehicular traffic, connecting loading and unloading areas of the plant to the public streets, shall be available. Employee parking areas and access roads close by the food processing plant shall be hard surfaced with a binder of tar, cement or asphalt.

(c) **Separation.** Frozen food preparation plants shall be completely separated from areas used as living quarters by solid, impervious floors, walls and ceilings with no connecting openings.

(d) **Water supply.** (1) The plant shall have an ample volume of potable water available from an approved public or private source. If a nonpotable water supply is necessary, it shall not be used in a manner which will bring it into contact with the product or product zone of equipment. Such nonpotable water systems shall be kept entirely separate from the potable water supply, and the nonpotable water lines shall be positively identified by a distinctive color. (2) All equipment shall be so installed and used that back siphonage of liquids into the potable water lines is precluded. (3) Hot and cold water in ample supply shall be provided for all plant clean-up needs. Hoses used for clean-up shall be stored on racks or reels when not in use.

(e) **Plant waste disposal.** The disposal of liquid wastes shall be to the public sewerage system, if available and permitted by local ordinances, or to a properly designed and installed private facility. Private liquid waste treatment facilities shall be approved by the health authority having jurisdiction.

(f) **General plant layout.** (1) Product preparation and processing (including freezing) departments shall be of sufficient size to permit the installation of all necessary equipment with ample space for plant operations and with unobstructed truckways for conveyances of raw materials and processed products. The plant shall be so arranged that there is a proper flow of product, without undue congestion or backtracking, from the time raw materials are received until the frozen, packaged article is shipped from the plant. (2) Raw material storage rooms and areas where preparatory operations, such as washing and peeling of fruits and vegetables and the evisceration of poultry, are carried on shall be separate from rooms or areas wherein frozen food is formulated, processed and packaged. Doors connecting various rooms or openings to the outside shall be tight fitted, solid and kept in a closed position by self-closing devices. (3) Facilities for holding the product under refrigeration until processed shall be provided. (4) Facilities for quick freezing the processed product efficiently shall be provided and so located as to be convenient to the food processing and

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packaging departments. Ample freezer storage shall be provided convenient to the quick freezing facilities; provided, when the frozen product is immediately removed from the establishment, such freezer storage shall not be required. (5) A separate room for storing inedible materials, such as fruit and vegetable peels, feathers and bones, pending removal from the plant shall be provided in a location convenient to the various preparation and processing areas. This waste storage room shall be of sufficient size to permit the proper storage of filled and empty metal or other relatively nonabsorbent refuse containers and their lids. It shall be equipped with an efficient power exhaust ventilation system, hot and cold water outlets and adequate floor drainage. The discharge from the exhaust system shall be located well away from fresh air inlets into the plant. (6) Packaging and labeling materials shall be stored in a separately enclosed space convenient to the packaging department. Packaging and labeling materials shall not be stored in the product processing and packaging departments, except that small quantities of such supplies as are necessary for maintaining continuity of operations is permissible in the processing and packaging departments. (7) Facilities for inedible products and catch basins shall be suitably located so as to avoid objectionable conditions affecting the preparation and handling of edible products. (8) A separate room or area and proper facilities for cleaning equipment such as trays, hand trucks and implements shall be provided in a location convenient to the processing department. A power exhaust system shall be provided to dispel steam and vapors from the room. (9) Dockage areas shall be of adequate size, constructed of impervious materials and so drained as to minimize the entrance into the plant of dust, dirt and other contaminants from the receiving and shipping operations. If live animals are received, a separate dock shall be provided for this purpose. (10) Well located, properly ventilated dressing rooms and toilet rooms of ample size shall be provided for employees. Dressing rooms shall be separated from adjoining toilet rooms by tight, full height walls or partitions. The toilet room shall not be entered directly from a work room, but through an intervening dressing room or a properly ventilated toilet room vestibule. The ventilation and lighting of toilet and dressing rooms; the ratio of toilets, of hand-washing facilities, and of urinals to the number of employees using such facilities, and the type of fixtures used and the manner of installing all plumbing in such rooms shall conform strictly to applicable state and/or local codes governing such matters. (11) Employees shall not eat in the food processing or packaging area.

(g) **Plant construction.** (1) Floors shall be constructed of durable material which is easily cleanable and skid resistant. Where floors are wet cleaned, they shall be sloped to drain. (2) Interior walls shall be of a smooth and washable surface applied to a suitable base. (3) Coves with radii sufficient to promote sanitation shall be installed at the juncture of floors and walls in all rooms. (4) Ceilings shall be of adequate height and of smooth, washable material. (5) Window ledges shall be sloped at least 45° to the interior to promote sanitation. (6) Frozen food plants and warehouses shall be so constructed as to be rodent resistant. (7) All exterior window and door openings shall be equipped with effective insect and rodent screens. Where doors in outside walls or food handling areas are used for loading

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or unloading, “fly chaser” fans and ducts or other effective means shall be provided at such doors to prevent the entrance of insects. (8) Dressed lumber shall be used for exposed interior woodwork. (9) All exposed wood surfaces shall be finished with nontoxic oil or plastic paint or treated with hot linseed oil or clear wood sealer. (10) Stairs in product handling departments shall be constructed with solid treads and closed risers and shall have side curbs of similar material, six inches high measured at the front edge of the tread. (11) Refrigerator doors and jambs shall be covered with rust-resisting metal securely affixed to the doors and jambs. Joints necessary for installation shall be welded, soldered or otherwise effectively sealed. The juncture of the metal covering on jambs and walls shall be sealed with a flexible type sealing compound. Doorways through which the product is transferred on overhead rails or hand trucks shall be sufficiently wide to permit free passage of the largest trucks or widest suspended product without contact with the jambs.

(h) **Plumbing and floor drainage.** (1) The minimum slope of the floor for drainage shall be one-eighth inch to one-quarter inch per foot toward a properly located drain. Floor drains shall be provided at the rate of one drain for each four hundred square feet of floor area. The type and size of floor drains and sanitary sewage lines used and the method of installing such facilities and other plumbing equipment shall conform strictly to state or local codes. (2) Hand-washing facilities shall be provided convenient to all locations where the product is prepared and processed. Each lavatory shall be supplied with hot and cold or warm running water; powdered or liquid soap in a suitable dispenser; an ample supply of single service towels and a suitable receptacle for used towels. Lavatories in work-rooms and toilet rooms shall be pedal operated. (3) Where sterilizers are required, they shall be of a size that will permit complete immersion of tools and other implements. Such sterilizing receptacle shall be equipped with a water line, means for heating the water, an overflow outlet and means for emptying the receptacle.

(i) **Lighting; ventilation.** (1) Work-rooms and employee dressing rooms shall have means for furnishing adequate natural light (approximately twenty-five per cent of the floor area in windows and/or skylights) and ventilation or an efficient air conditioning or mechanical ventilation system and adequate artificial lighting shall be provided. (2) Fresh air intakes for mechanical ventilation systems shall be equipped with effective replaceable filters to prevent the entrance of air-borne contaminants. Fresh air intakes shall be located well away from power exhaust system discharges and other sources of air-borne contaminants. (3) The general light intensities in product preparation, processing and packaging areas shall be not less than twenty foot-candles measured thirty inches above the floor. Where detailed visual tasks are required to assure a safe, wholesome product, the intensity of light on the surface of the product or product container shall be not less than fifty foot-candles. At least ten foot-candles of light shall be provided in all dressing and toilet rooms and at least five foot-candles in all other areas of the plant.

(Effective July 27, 1984)

Sec. 21a-61-4. Design and construction of frozen food processing equipment

(a) **Coverage.** (1) This section applies only to equipment acquired after April 10, 1962; provided, when processing equipment constitutes an immediate health hazard, it shall be subject to the provisions of this section. In modifying machinery and equipment existing on said date, efforts shall be made to conform to these specifications. (2) This section applies to the design, materials, construction and installation of equipment used in the processing, holding and packaging of ready-to-eat frozen food and the processing and holding of gravies, batters and other food ingredients containing eggs, milk, broth and other food components capable of supporting rapid bacterial growth. (3) Articles and/or materials shall be subject to the Food Additives amendment to the Federal Food, Drug and Cosmetic Act and clearance for their use is necessary thereunder. Notwithstanding the provisions of this section, nothing herein contained is intended to prohibit the use of a food additive under and in accordance with the terms of an effective regulation pursuant to the Federal Food, Drug and Cosmetic Act.

(b) **General principles.** The design, materials, construction and installation of frozen food equipment shall be easily accessible for cleaning and sanitization.

(c) **Equipment classification.** (1) Equipment used for the processing, conveying, holding, refrigeration and packaging of gravies, batters, or other food ingredients containing eggs, milk or broth, alone or in combination with other food ingredients, which are capable of supporting rapid bacterial growth shall have a finish of corrosion-resistant material and shall be of smooth finish and readily accessible for cleaning. This includes, but is not limited to, the following: Pumps, valves, pipe lines and their fittings, heat exchangers, homogenizers, containers, hoppers and fillers. (2) Equipment used in the processing, holding and conveying of foods or food ingredients which are intended to be incorporated in ready-to-eat frozen food shall have a finish of corrosion-resistant material and shall be of smooth finish and readily accessible for cleaning. This includes, but is not limited to, reservoirs, holding tanks, kettles, mixers for liquids, mixers and blenders for powders, dough mixers, flour handling equipment, fryers, cutters, dicers, slicers, cutting boards, pumps, valves, tanks, lines and fittings for liquid sugar, oils and shortening.

(d) **Materials.** (1) All surfaces within the food product zone shall be smooth and free from pits, crevices and loose scale and shall be relatively nonabsorbent. Surfaces shall be nontoxic and unaffected by food products and cleaning compounds. (2) The finish of corrosion-resistant (stainless steel, nickel alloy, etc.) surfaces shall be of 125 grit, properly applied, or the equivalent. (3) The finish of cast iron, cast and forged steel and cast nickel alloy shall not exceed a reasonable surface standard of roughness. (4) The use of galvanized surfaces shall be minimal and, where used, shall be of the smoothness of high quality commercial hot dip. (5) Copper and its alloys shall not be used in equipment where edible oils, liquid shortening, chocolate liquor and other fatty food products come in contact with the metal. (6) Cadmium shall not be used in any manner or form on the food equipment. (7) Lead shall not be used within or adjacent to the food product zone with the exception of its inclusion in dairy solder in an amount not to exceed five per cent. (8) Plastics shall be

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abrasion resistant, heat resistant to the degree needed for the product and for the cleaning process, and shatterproof and shall not contain free phenol, formaldehyde or a constituent which may result in the migration of any of the substances to the food or otherwise affect the characteristics of the food with which it comes in contact. (9) All gasketing and packing materials shall be relatively nonporous, relatively nonabsorbent and installed in a manner that results in a true fit to prevent protruding into the product zone or creating recesses or ledges between the gasketed joints. (10) Coatings used in the food product zone as a lining to prevent corrosion of the base material of food equipment shall be nontoxic, unaffected by, and inert to, the food in contact with it or cleaning preparations used on it. Such coatings shall be relatively nonabsorbent, odorless and tasteless.

(e) **Design and construction: Food product zone.** (1) All parts of the product zone shall be readily accessible or be readily removable for cleaning and inspection. (2) All parts of the food product zone shall be free of recesses, dead ends, open seams and gaps, crevices, protruding ledges, inside threads, inside shoulders and bolts or rivets which form pocket and patterns. (3) All permanent joints of metal parts shall be butt welded. (4) All welding within the food product zone shall be continuous, smooth, even and flush with the adjacent surfaces. (5) All interior corners shall be provided with a minimum radius of one-quarter inch, except where a greater radius is required to facilitate drainage or cleaning. (6) The equipment shall be constructed and installed to provide sufficient pitch so as to be completely self-draining. (7) Equipment which introduces air into the food product or uses air to convey the food product shall be fitted with a filter capable for withholding particles fifty microns or larger in size. Such filters shall be readily removable for cartridge replacement or cleaning. (8) Bearings shall be located outside the food product zone or outboard and shall be of the sealed or self-lubricated type. Those intended for use with a dry granular or a dry pulverized product directly adjacent to the food product zone shall be of the sealed type, without grease fittings. The bearings shall be installed flush to eliminate any recessed areas around the shaft within the food product zone. (9) Shaft seal assemblies and packing glands shall be outboard and shall be readily removable. The shaft seal or packing shall be retractable within a space between the assembly and bearing to facilitate easy removal of the sealing assembly and materials for cleaning and inspection. (10) All permanent screening and straining devices shall be readily removable for cleaning and inspection. They shall be designed to prevent replacement in an improper position. (11) Permanent screening and straining surfaces intended for use with a liquid or a semi-liquid product shall be fabricated from perforated metal. (12) Permanent screening and straining surfaces intended for use with a dry granular or a dry pulverized product shall be fabricated from perforated metal; provided wire screen of not less than thirty by thirty continuous mesh may be used. (13) All filtering surfaces shall be readily removable for cleaning and inspection. (14) Filter papers shall be of the single-service type. (15) Filter cloths and spun glass filters shall be launderable. (16) Hinges and latches shall be of the simple take-apart type. (17) Motors shall be of the totally enclosed finless type and shall be mounted on the equipment whenever possible. (18) Covers shall be provided on reservoirs, hoppers or other

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vessels, and they shall be readily removable and shall be fitted with drip protective devices or facilities to prevent foreign substances from falling into the product.

(f) **Design and construction: Non-food product zone.** (1) All safety or gear guards shall be removable for cleaning and inspection. (2) All external surfaces shall be free of open seams, gaps, crevices, unused holes and inaccessible recesses. (3) Horizontal ledges and frame members shall be kept to a minimum; external angles shall be rounded, and internal angles shall be avoided. (4) Where lubrication of equipment is required, provision shall be made to prevent leaking or dripping into the food product zone.

(g) **Installation of equipment.** (1) All equipment shall be installed on a foundation of durable, easily cleanable material. (2) Equipment shall be placed at least eighteen inches from walls and ceiling, or sealed watertight thereto. All portions of the equipment shall be installed sufficiently spaced above the floor on a minimum number of supporting members to provide access for inspection and cleaning, or be installed completely sealed (water-tight) to the floor. (3) Whenever equipment passes through walls or floors, it shall be sealed thereto or sufficient clearance shall be allowed to permit inspection, cleaning and maintenance. (4) Where necessary, drains and catch pans shall be provided and shall be of such dimensions as to collect all spill and drip and be readily accessible or readily removable for cleaning. (5) Where pipes pass through ceilings of processing areas, pipe sleeves shall be inserted in the floor above so that their upper periphery is at least two inches above the floor. (6) All electrical connections, such as switch boxes, control boxes, conduit and Bx cables, shall be installed a minimum of three-quarters inch away from the equipment and walls, or be completely sealed to the equipment or wall.

(Effective July 27, 1984)

Sec. 21a-61-5. Operating practices for the commercial manufacturer of frozen food

(a) **Handling and storage of materials.** (1) Foods. All food ingredients received at the plant shall be wholesome. Storage shall be in rooms completely separate from food preparation and processing operations. Storage conditions shall preclude contamination from rodents, insects and other sources. Temperature of storage shall be in accordance with the following practices: Ingredients requiring refrigeration shall be stored at an air temperature of 40°F. or lower; frozen ingredients shall be stored at an air temperature of 0° or lower. (2) Packaging materials. Storage shall be in rooms completely separate from food preparation and processing operations. Conditions of storage shall preclude contamination from rodents, insects and other sources. (3) General housekeeping. The plant and premises shall be maintained so as to present a neat and orderly appearance at all times.

(b) **Personnel hygiene.** (1) The services of an employee with any open sore or an exposed portion of the body or one afflicted with an infectious or contagious disease shall not be used; provided services of employees with finger cuts, or with bandages, finger cots and similar type coverings may be utilized on the condition that such employee wears rubber gloves. Any employee with an upper respiratory infection shall be assigned duties outside of the areas of food preparation, processing and packaging. (2) Visitors to food preparation,

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processing and packaging areas shall comply with employee requirements and such visits by unauthorized persons shall be restricted.

(c) **Practices for employees handling unpackaged food.** (1) Employees shall wear head covering and shall keep clothing in a clean condition consistent with the duty being performed. (2) Before beginning work, after each absence from post of duty, and after contact with non-sanitized surfaces, each employee shall: Wash his hands with liquid or powdered soap and warm water dispensed from a foot or elbow operated device; rinse his hands in a chlorinated spray or other approved sanitizing agent; dry his hands with single-service towels. (3) Employees shall minimize hand contact with food products. (4) The use of a common dip bowl or tank is prohibited. (5) If rubber gloves are used, they shall be cleaned and sanitized in accordance with hand washing specifications in subdivision (2) of this section. (6) Using tobacco in any form, chewing gum or eating in rooms where food products are stored, handled or prepared shall not be permitted.

(d) **Plant and equipment: Sanitation.** (1) Plant and equipment shall be clean when put into service. (2) All floors, tables, splash boards, work surfaces, equipment and utensils shall be cleaned and sanitized with approved agents and methods at the close of each shift. Critical areas and all food contact surfaces shall be cleaned and sanitized at least once during each shift. (3) Equipment such as pipes, pumps, fillers and valves shall be dismantled for cleaning and sanitizing; provided approved and effective in-place cleaning and sanitizing methods will be acceptable. (4) A thorough rinse with potable water shall follow any sanitizing operation that has been completed with a chemical sanitizing agent.

(e) **Preparation and processing.** (1) Fans, blowers or air cooling systems shall not move air from raw material or preparation rooms into processing rooms. (2) Only adequately cleaned, prepared raw materials shall be introduced into areas where frozen precooked foods are cooked and subsequently handled in processing operations. (3) Preparatory operations feeding to the packing line shall be so timed as to permit expeditious handling of consecutive packages in production and under conditions to prevent contamination, loss of quality or spoilage. (4) When batter, egg wash or milk wash is an ingredient, it shall be maintained at a product temperature not to exceed 45°F. Cracked or flaked ice used to rehydrate batters shall meet bacterial standards for potable water. Batter remaining in machines and equipment at cleanup time shall be discarded. (5) Breeding materials that have come in contact with batter and have been removed by screening shall be discarded. (6) Food ingredients or mixtures that are capable of supporting rapid bacterial growth shall be maintained either at a product temperature above 160°F. or below 45°F. (7) Cooked food such as meat, poultry, sauces and gravies shall be: (A) Refrigerated or incorporated into the finished product within one hour following preparation; (B) refrigerated within thirty minutes following preparation at an air temperature of 50°F. or less if the product is to be held from one to eight hours after preparation; (C) refrigerated within thirty minutes following preparation such that the internal temperature of the food product will be 40°F., or lower, within two hours of refrigeration if the food product has been comminuted or sliced, or is a liquid, and if the food is to be held more than eight hours. Large solid food

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components such as those that must be cooled before slicing shall be refrigerated at an air temperature of 40°F. or lower. (8) Trays, pans or other containers of ingredients destined for incorporation into the finished product shall be protected with a clean cover unless these ingredients are used within thirty minutes of preparation. The cover shall not be of porous material. (9) Permanently legible code marks shall be placed on each immediate container or package at the time of packing. Such code marks, as devised by management, shall include the date of packing and the establishment where packed. (10) The packaged product shall be placed in the freezer within thirty minutes of packaging. Placement of packages in cases before freezing is prohibited. (11) Refuse from the food operations shall be promptly placed in containers that are prominently marked "Refuse" and equipped with lids. The handling of refuse shall be done in such a manner as not to constitute a nuisance. All refuse shall be removed from the premises on a daily basis and in such a manner as not to contaminate food products being manufactured within the plant. Refuse containers shall be thoroughly cleaned immediately after each emptying.

(f) **In-plant freezing.** (1) During the freezing cycle products shall be cooled to 50°F. or lower within two hours and to 0°F. or lower within thirty-six hours. (2) Products shall be frozen by approved commercial methods. (3) When necessary, products shall be protected so that dehydration and discoloration will not occur during the freezing cycle. (4) The freezer shall be precooled to an air temperature of 0°F. before loading. However, during loading, the freezer may rise to temperatures above 0°F. for short periods of time. (5) If cold air is used as the freezing medium, the product shall be arranged by staggering the individual items or by employing dunnage, spacers or other suitable methods to permit satisfactory circulation of cold air around the products. The cold air shall be circulated by a positive method; natural air circulation is not satisfactory. (6) The freezer and associated equipment used for handling the product shall be maintained in a clean and sanitary condition at all times. (7) A suitable indicating or recording instrument shall be used to measure the temperature of the cooling medium (i.e., air, liquid, refrigerated plates or pipe coils). (8) Packaged items are to be frozen in a manner that will result in a minimum amount of bulging or distortion. (9) After the freezing cycle, the frozen product shall be transferred to a storage facility as quickly as possible.

(Effective July 27, 1984)

Sec. 21a-61-6. Transportation

(a) **Equipment.** (1) Vehicles of transportation shall be equipped: (A) With a combination of insulation and mechanical refrigeration system, or other refrigeration methods or facilities, capable of maintaining an air and product temperature of 0°F., or lower, while loaded with any frozen food; and (B) with a thermometer, or other appropriate means of temperature measurement indicating air temperature inside the vehicle. The dial or reading element of the thermometer shall be mounted on the outside of the vehicle. (2) Vehicles used for route delivery shall comply with all equipment provisions herein specified for vehicles of transportation and shall be equipped with curtains or flaps in the doorway area,

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or with port doors, to maintain refrigeration during stops.

(b) **Handling practices for over-the-road transportation.** (1) Vehicles shall be precooled to an air temperature of 20°F., or lower, before loading. (2) Frozen food shipments shall not be accepted for transportation when the internal product temperature exceeds 0°F. (3) Frozen food shall be loaded within a vehicle of transportation to provide for free circulation of refrigerated air at the front, rear, top, bottom and both sides of the load, except for vehicles of envelope type construction wherein refrigerated air circulates within walls of such vehicles. (4) The mechanical refrigerating unit of vehicles shall be turned on and doors of vehicles shall be kept closed during any time interval when loading or unloading operations cease. (5) The average product temperature of any shipment of frozen food shall be determined during loading and unloading by adequate temperature readings.

(c) **Handling practices for route delivery.** In addition to all provisions specified in subsection (b) of this section, the following provisions shall be met: (1) Each lot for individual consignment shall be refrigerated by means of mechanical refrigeration, dry ice, or by any other means capable of maintaining an air and product temperature of 0°F., or lower; (2) insulated containers shall be precooled to a temperature of 20°F., or lower, before being loaded with frozen food; and (3) doors of vehicles shall be kept closed during any time interval that loading or unloading operations cease.

(d) **Sanitary provisions.** (1) All interior surfaces of vehicles and devices used for transporting frozen food shall be clean and free of objectionable odors before being loaded with frozen food. (2) Frozen food shall be securely packaged, or wrapped, in a sanitary manner before they are accepted for transportation.

(Effective July 27, 1984)

Sec. 21a-61-7. Warehousing

(a) **Equipment.** (1) Each warehouse shall be equipped with suitable mechanical refrigeration capacity to maintain, under extreme outside temperature and peak load conditions, an air temperature of 0°F., or lower. (2) Each storage room and part thereof shall be maintained at an air temperature of 0°F., or lower. (3) Each storage room shall be equipped with a thermometer or other temperature measuring device which is easily visible. (4) The sensing element of thermometers and other temperature measuring and recording devices shall be located not more than six feet or less than five feet from the floor and not in a direct blast of refrigerated air or near entrance doors. When indicating thermometers only are used, they shall be read and recorded at least once every twenty-four hours during each calendar day. (5) Recording thermometers equipped with charts shall have a chart perforator. Charts so used shall designate an operating range of at least 10° above and 10° below 0°F. in graduations of one degree. (6) The use of electric or hand wound clocks, as well as twenty-four-hour or seven-day charts, for recording thermometers shall be optional at the operator's discretion. (7) Each chart, or record of observed temperatures, shall be dated, showing the time interval covered thereby, and shall be kept on file for a period of at least one calendar year. (8) Each breakup room shall be maintained at a temperature not

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exceed 20°F.

(b) **Handling practices.** (1) The operator of a warehouse shall not accept custody of a lot or shipment of frozen food if internal product temperature exceeds 0°F., except as provided in section 21a-61-2 and except where such exception is duly recorded. (2) Notwithstanding the prohibition of subdivision (1), custody of lots with an internal product temperature in excess of 10°F. may be accepted by the operator on request of the owner of such lot, provided such foods shall be detained from sale and the temperature of such product shall be promptly returned to and maintained at 0°F., or lower, for the purpose of maintaining residual quality pending chemical, bacteriological or organoleptic examination. (3) Before a lot of frozen food is placed in storage, it shall be marked, or stamped, with a code for effective identification. (4) Frozen food in storage shall be placed on pallets, racks or skids and shall be stored no closer than eighteen inches to the ceiling and shall be otherwitored so as to permit free circulation of refrigerated air. (5) Frozen food shall be stored under good sanitary conditions that preclude injury and contamination from, or to, other food held within the warehouse. (6) During the defrosting of overhead coils in storage rooms, stacks of frozen food shall be effectively protected from contamination by condensation, drip or leakage. (7) Break-up rooms shall not be used for storage. (8) At the time of its removal from warehouse custody, the internal product temperature of frozen food shall not exceed 0°F.

(c) **Sanitary provisions.** (1) The floors, walls and ceiling of a warehouse shall be maintained in a good sanitary condition. (2) The premises of a warehouse shall be maintained in a good sanitary condition. (3) (A) Warehouses shall have waterflush toilets so located as to be convenient to employees. The toilet room or rooms shall be well lighted and ventilated and shall be maintained in a sanitary condition. The doors of all toilet rooms shall be full-length and self-closing. (B) Adequate hand-washing facilities, including hot and cold or warm running water, powdered or liquid soap in a suitable dispenser and single service towels, shall be provided adjacent to all toilet rooms. The use of a common towel is prohibited. Washrooms shall be well lighted and ventilated and shall be maintained in a sanitary condition. (C) Warehouses shall have a dressing room or rooms for the changing and hanging of wearing apparel. If individual lockers are provided, they shall be well vented and maintained in a clean, sanitary condition and shall be free from disagreeable odors. The dressing room or rooms shall be adequately lighted and ventilated and shall be maintained in a clean, sanitary condition.

(Effective July 27, 1984)

Sec. 21a-61-8. Retail

(a) **Equipment.** (1) Each storage facility shall be equipped with suitable mechanical refrigeration capacity to maintain, under extreme outside temperature and peak load conditions, an air temperature of 0°F., or lower. (2) When storage facilities of the cabinet type are used: (A) They shall be defrosted as frequently as necessary to maintain refrigeration efficiency specified; and (B) they shall be equipped with a thermometer

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indicating a representative air temperature. (3) When storage facilities of the walk-in freezer type are used: (A) Frozen food in storage shall be on pallets, racks or skids and shall be stored no closer than eighteen inches to the ceiling and otherwise stored so as to permit free circulation of refrigerated air. (B) They shall be equipped with a thermometer, the sensing element of which shall be located within the upper third of the distance between the floor and ceiling. Such sensing elements shall not be placed in a direct blast of air from cooling units, cooling coils and heat exchange devices, or near the entrance door; and (C) they shall be equipped with an automatic mechanism for defrosting refrigerated coils when forced air blower type of refrigeration is used. (D) All frozen food display cases shall be designed, constructed and equipped with mechanical refrigeration facilities capable of maintaining an air temperature of 0°F. or lower. (E) Frost on refrigerator coils and in air passages of display cases shall be removed as frequently as necessary to maintain refrigeration efficiency. (F) Each display case shall be equipped with a thermometer, the sensing element of which shall be located in an appropriate place within the path of refrigerated air being returned to the coils. (G) The product load line shall be designated by a distinctive line at the inside terminal ends of each display case, and such lines shall be at the highest point of discharge and return of refrigerated air. (H) Each display case shall be equipped with separators to provide false walls located a minimum of one-half inch from terminal ends to provide for free circulation of refrigerated air between such terminal ends and the displayed product. (I) All display cases in a retail outlet shall be so placed as to be relatively free of air currents resulting from door drafts, electric fans and other factors that adversely deflect the current of refrigerated air within the display case, and of heat elements, such as lights, heating units and related devices that tend to raise the temperature of refrigerated air within the display case.

(b) **Handling practices.** (1) Frozen food shall not be accepted for delivery by a retail outlet when the internal product temperature exceeds 0°F., except as provided in section 21a-61-2 and except where such exception is duly recorded. (2) All frozen food received at a retail outlet shall be immediately placed in storage facilities. (3) Each retail outlet shall be equipped with storage facilities of sufficient cubic displacement to accommodate the storage of frozen food. (4) Frozen food shall not be placed above the product food lines within any display case. (5) All frozen food in a retail outlet shall be stored and displayed under good sanitary conditions. (6) Retail outlets shall employ the first-in first-out basis of inventory control.

(Effective July 27, 1984)

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Subject

Specifications and Test Standards for Clinical Thermometers

Inclusive Sections

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Specifications and Test Standards for Clinical Thermometers

Sec. 21a-63-1. Application for permit to sell clinical thermometers in the state of Connecticut

Each manufacturer applying for authority to sell thermometers in the state of Connecticut shall comply with the following requirements before a permit is granted:

(a) Such application shall be made to the State Department of Consumer Protection on application forms to be furnished by the department.

(b) At the time of making application the manufacturer shall submit a representative sample of his clinical thermometers, which shall be taken at random from his stock. Such representative sample shall consist of two hundred clinical thermometers. More clinical thermometers may be requested for examination before the permit is granted.

(Effective February 29, 1988)

Sec. 21a-63-2. Granting of permit

After any manufacturer of mercury-in-glass clinical thermometers has fulfilled all the requirements of section 21a-63-1, the State Commissioner of Consumer Protection shall grant a permit to such manufacturer to sell clinical thermometers of his manufacture that meet the specifications and tolerances herein established. For the purposes of these requirements, specifications and tolerances, an individual, a firm or a corporation shall not be considered a manufacturer unless engaged in the business of engraving, either by etching and filling or by staining, and testing clinical thermometers.

(Effective February 29, 1988)

Sec. 21a-63-3. Factory records

Each permittee shall keep on file for at least two years complete records of each clinical thermometer which has been sold in the state of Connecticut, the record to include either a serial number or code which indicates the specific period, not to exceed 90 days, in which the thermometers were calibrated, name and address of the purchaser, and the date of sale of each lot of thermometers sold. These records shall be available to a representative of the State Department of Consumer Protection at any time upon request.

(Effective February 29, 1988)

Sec. 21a-63-4. Guarantee

Each manufacturer of clinical thermometers shall furnish to the Chief of the Weights and Measures Division of the State Department of Consumer Protection, within thirty days of the date of sale, a sales record for thermometers sold in this state. This record shall include the name and address of the purchaser, the date of sale and the variety name of each lot of thermometers, together with the number of thermometers in each consignment.

(Effective February 29, 1988)

Sec. 21a-63-5. Forfeiture of permit by manufacturer

The testing records of a manufacturer shall show that he has been actively engaged in the business of selling clinical thermometers for use in the state of Connecticut within the previous two-year period in order to entitle him, at any time, to retain a Connecticut permit.

(Effective February 29, 1988)

Sec. 21a-63-6. Termination of permit

Any permit granted under sections 21a-63-1 to 21a-63-12, inclusive, and all rights and privileges pertaining thereto, shall terminate if the holder of the permit at any time or for any cause ceases to be a manufacturer of clinical thermometers.

(Effective February 29, 1988)

Sec. 21a-63-7. Manufacturer's standards and certificates

A manufacturer holding or applying for a Connecticut permit may at any time be required to submit to the State Department of Consumer Protection for test or examination such clinical thermometer standards or certificates as may be deemed necessary for carrying out any of the provisions of section 21a-63 of the General Statutes.

(Effective February 29, 1988)

Sec. 21a-63-8. Purpose

The purpose of this standard is to provide a specification and methods of testing clinical thermometers as a basis for certification of quality and accuracy; to assure the purchaser that the thermometer has been tested and found to meet the requirements of a recognized standard.

(Effective February 29, 1988)

Sec. 21a-63-9. Scope

This standard applies to maximum self-registering mercury-in-glass thermometers of the types commonly used for measuring body temperatures. Each clinical thermometer legal for sale in Connecticut shall meet the requirements and tests for: bulb and stem glasses, mercury, legibility and permanency of markings, dimensions, temperature scale ranges, graduations, thermometer stability, ease of resetting, retention of temperature indication, and accuracy of scale reading.

(Effective February 29, 1988)

Sec. 21a-63-10. Markings

Each clinical thermometer marked by the manufacturer shall be engraved with the legible characters in the following order: Serial number or code; and manufacturer's name, initials or trade-mark. If a variety name is engraved on the thermometer, it shall follow the manufacturer's name, initials or trademark. A cap may be attached to the top of the stem,

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provided it shall not cover up any markings, graduations or imperfections.

(Effective February 29, 1988)

Sec. 21a-63-11. Adoption of standards

Standard specification ASTM E 667-79 of the American Society of Testing and Materials, except for section 5.6, 7 and 7.1 of said specification, is adopted and herein incorporated by reference as setting forth standards for the manufacture and testing of clinical thermometers in this state.

(Effective July 27, 1984)

Sec. 21a-63-12. Test for entrapped gas

Gas in bulb. Thermometers in which inspection shows the presence of gas in the bulb shall be rejected.

(Effective July 27, 1984)

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Subject

Safe Handling and Disposal of Hypodermic Needles and Syringes

Inclusive Sections

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Safe Handling and Disposal of Hypodermic Needles and Syringes

Sec. 21a-66-1. Definitions

(a) **Hypodermic needles and syringes** means needles, syringes and any other types of intravascular device including but not limited to indwelling catheters and introducers, except that needles which are specifically used to administer antineoplastic agents shall be handled in accordance with existing Department of Environmental Protection Regulations for the handling of such wastes.

(b) **Biomedical Waste** means untreated solid waste which requires special handling as defined in Sec. 22a-207 (17) of the Connecticut General Statutes.

(c) **Treatment** when used in connection with biomedical waste, means any method, technique, or process which is designed to change the character or composition of any biomedical waste so as to render such waste non-infectious, non-injurious, safer for storage, for transport, and reduced in volume.

(Effective May 19, 1989)

Sec. 21a-66-2. Safety procedures concerning hypodermic needles and syringes

Each health-care institution licensed pursuant to Chapter 368v of the Connecticut General Statutes, each laboratory licensed pursuant to Section 19a-30 of the Connecticut General Statutes, and all other generators of biomedical waste as defined in Section 22a-207 of the Connecticut General Statutes, as amended, shall forthwith establish and implement procedures for the handling and disposal of hypodermic needles and syringes in accordance with the following safety and control measures.

(a) Used hypodermic needles and syringes shall be placed intact directly into rigid puncture-resistant containers and the following procedure shall be followed:

(1) Needles shall not be resheathed, purposely bent, broken, removed from disposable syringes, or otherwise manipulated by hand;

(2) Notwithstanding the requirement set forth in Subsection (a) (1), injectable equipment having self-contained secondary precautionary type sheathing devices may be utilized in accordance with its manufacturer's directions, and resheathing may occur when technical procedure involved requires resheathing as part of that procedure;

(3) Containers shall be located in close proximity to the area in which hypodermic needles and syringes are used to minimize the hazards of injury or transmission of infection during transport;

(4) The container lid opening shall be a one way system to prevent spillage, and this shall render the items contained therein nonreuseable;

(5) Containers shall be maintained under secure conditions at all times; and

(6) Prior to treatment, containers shall be stored in a designated area accessible only to authorized personnel.

(b) Containers of hypodermic needles and syringes shall be considered to be biomedical waste, and shall be treated to render them non-recoverable in accordance with any existing Department of Environmental Protection Regulations regarding biomedical waste or in

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accordance with any other methods specifically approved by the Commissioner of Consumer Protection in consultation with the Commissioners of Health Services and Environmental Protection.

(c) If treatment is not done onsite, these wastes shall be safely transported in sealed, impervious containers to another facility for appropriate treatment.

(d) Personnel involved in the handling and disposal of hypodermic needles and syringes shall be informed of the potential health and safety hazards, and trained in the appropriate handling and disposal procedures.

(e) Each facility shall monitor staff performance for adherence to the established handling and disposal procedures.

(f) Policy for disposal of these wastes by a health care facility shall be available for review by the Department of Health Services or the Commissioner of Consumer Protection.

(Effective May 19, 1989)

Sec. 21a-66-3. Purchase, possession, control and use of hypodermic needles and syringes

(a) The purchase, possession, control, and use of hypodermic needles and syringes by commercial or industrial firms pursuant to Section 21a-65 (a) (6) of the Connecticut General Statutes shall be considered to be authorized by the Commissioner of Consumer Protection provided that such businesses attest to the following in a written statement which they shall provide to the commissioner:

- (1) that there exists an essential need for such devices in any function of their operation;
- (2) that there are no devices, tools, or equipment modifications which may be used as an alternative to the use of hypodermic needles and syringes;
- (3) that there shall be maintained only those quantities of hypodermic needles and syringes which are essential for normal efficient operations;
- (4) that security safeguards and inventory control systems have been established which are adequate to detect any loss or diversion of hypodermic needles and syringes; and
- (5) that access to stocks of hypodermic needles and syringes is limited to only those employees who have a legitimate need to handle these devices in the normal course of business.

(b) It shall be within the discretion of the Commissioner to determine whether such firms meet the requirements of subsection (a) of this section.

(Effective May 19, 1989)

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Unit Pricing of Consumer Commodities

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Unit Pricing of Consumer Commodities

Sec. 21a-75-1. Definitions

(a) “Commissioner,” as used in these regulations, means the Commissioner of Consumer Protection.

(b) “Consumer Commodity” means any food, drug, device, cosmetic, or other article, product, or commodity of any other kind or class, except drugs sold by prescription only, which is customarily produced for sale to retail sales agencies or instrumentalities for consumption by individuals, or use by individuals for purposes of personal care or in the performance of services ordinarily rendered in or around the household, and which usually is consumed or expended in the course of such consumption or use.

(c) “Unit Price” of a consumer commodity means the retail price of a consumer commodity expressed in terms of the retail price of such commodity per unit of weight, measure or count, computed to the nearest whole cent or fraction thereof.

(d) “Point of Sale” as used in these regulations, means the point at which consumer commodities are offered and displayed for retail sale in such a manner that the consumer may examine and select commodities for purchase without the assistance of sales personnel.

(e) As used in these regulations, the terms food, drug, device and cosmetic are defined as in Section 21a-92 of the Connecticut General Statutes:

(i) “Food” means (1) articles used for food or drink for man or animals, and (2) chewing gum, and (3) articles used for components of any such article;

(ii) “Drug” means (1) articles recognized in the official United States pharmacopoeia, official homeopathic pharmacopoeia of the United States or official national formulary, or any supplement to any of them; (2) articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; (3) articles, other than food, intended to affect the structure or any function of the body of man or any other animal; and (4) articles intended for use as a component of any articles specified in this subsection; but shall not include devices or their components, parts or accessories;

(iii) “Device” means instruments, apparatus and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals, or (2) to affect the structure or any function of the body of man or other animals;

(iv) “Cosmetic” means (1) articles intended to be rubbed, poured, sprinkled or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.

(Effective July 27, 1984)

Sec. 21a-75-2. Persons to whom regulations apply

(a) Any person who sells or offers or exposes for sale at retail any of the consumer commodities designated in Section 6 of these regulations shall disclose to the consumer the price per unit of weight or measure or count and the total price, as required by Section 4 of

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the regulations.

(b) Owner-operated single retail stores are exempt from these regulations. An “owner-operated single retail store” shall meet the following requirements:

(i) The principle owner of the owner-operated single retail store must hold more than 50% of the ownership interest of the store and may not have any ownership interest whatsoever in any other retail store in the State of Connecticut which sells consumer commodities covered under the unit pricing statute; and

(ii) At least one person who has an ownership interest in the store, or a member of his immediate family, must be employed at the premises of the store during all hours that the store is open to the public, or at least forty hours per week, whichever is less. For purposes of this section, “immediate family” means the owner’s parent, son, daughter, husband, wife, brother or sister.

(Effective July 28, 1992)

Sec. 21a-75-3. Exempt products

(a) Beverages subjected to or complying with packaging or labeling requirements imposed under the Federal Alcohol Administration Act.

(b) Products which are required to be marked individually with the cost per unit weight under the provisions of Section 42-115l of the Connecticut General Statutes.

(c) Such consumer commodities which are sold in units of even pounds, pints, quarts or gallons, and which have a retail price plainly marked thereon; but only the particular consumer commodities sold in such units shall be exempt.

(d) Different products co-mingled in one receptacle or package for the purpose of a one-price sale.

(e) Products sold in one size limit only.

(f) Snack foods such as cakes, candies, or chips, sold in packages under five ounces in weight.

(Effective July 27, 1984; Amended September 26, 1996)

Sec. 21a-75-4. Method of disclosure

(a) All retail establishments subject to these regulations shall disclose the price per measure to the consumer by the attachment of a tag or label of any of the following colors on the item itself, or on the shelf or at any other point of sale immediately below the item, or above the item, so as to be conspicuously visible to the consumer. The permissible colors for such tag or label are red, blue, green, orange, yellow, or brown. The color white may be used in conjunction with any of these other colors, but white lettering on clear plastic or cellophane wrappers may not be used. In the alternative, a retailer may disclose the price per measure to the consumer by means of an electronic device, referred to in subsection (f) of this section, which must be placed on the shelf or at any other point of sale immediately below the item, or above the item, so as to be conspicuously visible to the consumer. Such electronic device shall utilize blue color for the retail price and orange color for the unit

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price.

(b) The tag, label or electronic device shall contain the following three elements:

(i) The words “Unit Price” shall appear as a heading, with the unit price always appearing above, or to the left of, the then-selling price;

(ii) The price per measure expressed in terms of dollars or cents as applicable, carried to three digits. If the price is over \$1.00, it is to be expressed to the nearest full cents, provided that the said price is rounded off from .005 and over to the next higher cents; and if .004 or less cent, it be carried to three digits. Examples: “25.3 per pound; \$1.67 per quart”; and

(iii) The applicable unit of weight or measure or count.

(c) The following additional information may appear on the tag, label or electronic device at the option of the individual retailer:

(i) The description of the commodity being sold by item and size;

(ii) In items such as paper products, the applicable “ply” count or thickness may be included; and

(iii) Such logistical information which the retail establishment requires, such as order codes, number of rows, or shelf capacity.

(d) If the consumer commodity is not conspicuously visible to the consumer or where the display space used for a particular consumer commodity is inadequate to set forth separate price legends, as required by these regulations, a list of the prices per measure shall be conspicuously posted at or near the point of sale or the point of display; or the price per measure may be stamped or affixed to the item itself.

(e) The price per measure shall be displayed in type no smaller than that used for the retail price of the item, but in no event shall the price per measure appear in size less than pica type. When a retail food establishment employs display material at the point of sale and the retail price appears thereon in sizes larger than pica type, the unit price information required by these regulations shall conspicuously appear thereon and shall appear in size no less than pica type or 1/4 the size numerals used for the retail price, whichever is greater.

(f) An electronic shelf labeling system which uses electronic devices to only display the unit price information required by subsections (b), (c), and (d) of this section may be utilized with the approval of the commissioner. In seeking the commissioner’s approval, a retailer must send in a written request for such approval, along with a description of the proposed electronic shelf labeling system. In deciding whether to approve the electronic shelf labeling system, the commissioner’s review shall include but not be limited to the overall appearance of the device and its capacity to transmit the unit pricing information to consumers. If a retailer utilizes an electronic shelf labeling system, such system must be constructed and affixed in such a manner so as to prevent alteration or movement of the electronic device or display information by consumers.

(Effective July 28, 1992; Amended September 26, 1996)

Sec. 21a-75-5. Price per measure

(a) The price shall be designated as per pound or as per ounce, whichever offers the most

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meaningful basis of comparison for the consumer, on all commodities whose net quantity is customarily expressed in units of pounds or ounces or both, provided that the same unit of measure is used for the same commodity in all sizes sold in such retail establishment.

(b) The price shall be designated as per pint, quart or gallon or ounce or liter for commodities whose net quantity is expressed in units of pints, quarts, gallons or fluid ounces or ounces or liters, or a combination thereof, provided, that the same unit of measure is used for the same commodity in all sizes sold in such retail establishment.

(c) The price shall be designated as per 50 feet or per 100 square feet, or per 100 feet as appropriate, for commodities and items whose net quantity is customarily expressed in units of feet, inches, square feet or square yards, or per product measurement or whose net quantities are expressed in units of area or length provided, that the same unit of measure is used for the same commodity in all sizes sold in such retail establishment.

(d) The price shall be designated as per 1 unit or 50 units or 100 units of commodities, whose net quantity is expressed by a numerical count provided, that the same unit of measure is used for the same commodity in all sizes sold in such retail establishment.

Required Units of Measure for Unit Price Designation

The following list of products indicates the corresponding unit of measure which is required to be used in the designation of the unit price of such products by all retail food establishments subject to the unit price regulations. As a general rule, all dry bulk products are unit priced by the pound; all products sold in aerosol cans are unit priced by the pound; and the majority of the liquid products are unit priced by pints, quarts or gallons. There are several products on this list which may be unit priced by different units of measure, provided that the same unit of measure is used for the same commodity in all sizes sold in a single retail food establishment.

(Effective July 27, 1984; Amended September 26, 1996; Amended February 2, 2007)

Sec. 21a-75-6. Products regulated

(a) Group 1:

<u>Product</u>	<u>Unit Measure</u>
Detergents:	
liquid	pint or quart or ounce or gallon
dry	pound or ounce
Household cleansers, waxes, polishes and deodorizers	
liquid	pint or quart or ounce or gallon
dry	pound or ounce
aerosols	pound or ounce
Cereals	pound or ounce
Instant breakfast foods	pound or ounce

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Butter	pound or ounce
Oleomargarine	pound or ounce
Coffee, instant and ground	pound or ounce
Cocoa, chocolate syrups	pint or quart or ounce or gallon if sold by volume pound or ounce if sold by weight
Tea:	
bags	per 50 or 100 units or per 1 count
bulk	pound or ounce
instant	pound or ounce
Jellies and jams	pound or ounce
Peanut butter	pound or ounce
Mayonnaise	pint or quart or ounce or gallon
Paper products including napkins, paper towels and tissues	per 50 or 100 units or per 1 count or per 1 or 50 or 100 square feet/foot per 1 count
Aluminum wraps, plastic wraps and waxed paper	per 1 or 50 or 100 square feet/foot
Paper and plastic bags, plates and cups	per 1 or 50 or 100 units or per 1 count
Baby foods:	
solids	pound or ounce
juices	pint or quart or ounce or gallon

(b) Group 2:

<u>Product</u>	<u>Unit Measure</u>
Detergents:	
liquid	pint or quart or ounce or gallon
dry	pound or ounce
Household cleansers, waxes, polishes and deodorizers	
liquid	pint or quart or ounce or gallon
dry	pound or ounce
aerosols	pound or ounce
Cereals	pound or ounce

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Instant breakfast foods	pound or ounce
Butter	pound or ounce
Oleomargarine	pound or ounce
Coffee, instant and ground	pound or ounce
Cocoa, chocolate syrups	pint or quart or ounce or gallon if sold by volume pound or ounce if sold by weight
Tea:	
bags	per 50 or 100 units or per 1 count
bulk	pound or ounce
instant	pound or ounce
Jellies and jams	pound or ounce
Peanut butter	pound or ounce
Mayonnaise	pint or quart or ounce or gallon
Paper products including napkins, paper towels and tissues	per 50 or 100 units or per 1 count or per 1 or 50 or 100 square feet/foot per 1 count
Aluminum wraps, plastic wraps and waxed paper	per 1 or 50 or 100 square feet/foot
Paper and plastic bags, plates and cups	per 1 or 50 or 100 units or per 1 count
Baby foods:	
solids	pound or ounce
juices	pint or quart or ounce or gallon
(c) Group 3:	
Fruits and vegetables:	
canned	pound or ounce
jarred	pound or ounce
boxed	pound or ounce
Juices	pint or quart or ounce or gallon
Shortenings	pound or ounce
Flours	pound or ounce
Cooking oils	pint or quart or ounce or gallon
Canned fish and canned meats	pound or ounce

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Deodorants	pound or ounce
Shampoos	pint or quart or ounce or gallon
Cold cuts	pound or ounce
Fish products and meat	pound or ounce

(Effective July 28, 1992; Amended September 26, 1996; Amended February 2, 2007)

Sec. 21a-75-7. Extension of time for compliance

Any retail establishment which is unable to comply with these regulations may make written application to the Commissioner for permission to extend such time for compliance for a period not to exceed thirty days. Such retail establishment shall set forth, in as much detail as possible, the reasons for its inability to comply. The Commissioner may extend such period from time to time, upon such terms and conditions as may be deemed reasonable.

(Effective July 27, 1984)

Sec. 21a-75-8. Responsibility for compliance

In the event of a violation of these regulations, the owner, the manager, or the person in charge of such retail establishment, and the person employing such manager or person in charge, where applicable, shall be deemed to be responsible for compliance by such retail establishment with the requirements of these regulations.

(Effective July 27, 1984)

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Subject

Universal Product Coding/Marking of Retail Price

Inclusive Sections

§§ 21a-79-1—21a-79-7

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Universal Product Coding/Marking of Retail Price

Sec. 21a-79-1. Definitions

For purposes of Sections 21a-79-1 to 21a-79-7, inclusive, of these regulations, the following terms shall have the meanings indicated:

(a) “Retail Price” is the price marked on the consumer commodity at which said consumer commodity is to be sold to the customer;

(b) “Retailer” means any person, firm, partnership, association or corporation which utilizes universal product coding in totaling a retail customer’s purchase; and

(c) “Exempted Consumer Commodity” means a consumer commodity which has been exempted from the requirement that each item of such consumer commodity be marked with its retail price.

(Effective October 25, 1993)

Sec. 21a-79-2. Unmarked consumer commodities

Any consumer commodity not properly marked with the retail price or for which the retailer has not been granted an item price exemption in accordance with section 21a-79 (b) (4) of the Connecticut General Statutes, shall be removed from sale until properly marked.

(Effective May 23, 1988; Amended October 1, 2007)

Sec. 21a-79-3. Improperly marked or scanned consumer commodities

(a) If the retail price posted or marked on the consumer commodity is higher than that displayed by the scanner, the lower price will prevail.

(b) If the retail price posted or marked on the consumer commodity is lower than that displayed by the scanner, then one item of such consumer commodity, up to a value of twenty dollars, shall be given to the consumer at no cost.

(Effective May 23, 1988; Amended October 1, 2007)

Sec. 21a-79-4. Test scanning

(a) Any person, firm, association or corporation which utilizes universal product coding in totaling a retail customer’s purchases shall make available to the customer a scanner, capable of reading a universal product code bar, so as to allow the consumer an opportunity to personally identify the price of any item offered for sale. The specific scanner must be clearly identified as available for consumer use and may be one of several such devices utilized by consumers to actually purchase items from the retailer. The use of the consumer designated scanner may be limited during times of maximum register use, and the scanner designated for consumer use shall be the last scanner placed into service to register sales of items when a retailer determines that all scanning check-out registers must be in use.

(b) If an item price exemption has been granted to a retailer in accordance with section 21a-79 (b) (4) of the Connecticut General Statutes, the retailer shall also make available a

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consumer price test scanner, approved by the commissioner and located prominently in an easily accessible location for each twelve thousand square feet of retail floor space, or fraction thereof.

(Effective May 23, 1988; Amended October 1, 2007)

Universal Product Coding/Exemptions from Marking of Retail Price

Sec. 21a-79-5. Exempted consumer commodities

The following consumer commodities need not be marked with their retail prices:

- (1) canned cat food;
- (2) milk;
- (3) powdered gelatin and pudding dessert mixes;
- (4) canned tuna fish;
- (5) fresh shell eggs;
- (6) ice cream in one-half gallon, quart, and pint sizes;
- (7) frozen concentrated juices and fruit drinks;
- (8) toilet tissue packaged in single rolls;
- (9) baby food packed in glass jars;
- (10) individually packed candy and chewing gum offered for sale at cash register/checkout locations;
- (11) salad dressings, in either bottles or packets; and
- (12) refrigerated yogurt in half pint sizes (8 ounces) or less, sold individually or in packs.

(Effective October 25, 1993; Amended November 3, 2003)

Sec. 21a-79-6. Signs required to inform consumers of exemption and retail price

(a) Exempted consumer commodities shall have a three-inch by five-inch sign conspicuously placed adjacent to the display of such consumer commodity, with a frequency of one sign for every six linear feet of display, or fractional part thereof. Such sign shall: (1) contain a statement that the consumer commodity has been exempted from the requirement that each such consumer commodity be individually marked with its retail price, and that, in the event that an exempted consumer commodity registers at the cash register or checkout terminal at a retail price which is higher than the retail price as stated, one item of such exempted consumer commodity up to a value of twenty dollars, shall be given to the consumer at no cost; and (2) not contain any additional text, including but not limited to store or promotional slogans, names, or advertising.

(b) Each exempted consumer commodity shall have its current retail price disclosed on a tag or label directly adjacent to the consumer commodity, on the shelf on which the commodity is displayed. For purposes of this subsection, the tag or label provided pursuant to Section 21a-74 (b) (1) of the Connecticut General Statutes shall be deemed to satisfy the requirements of this subsection.

(Effective October 25, 1993; Amended October 1, 2007)

Sec. 21a-79-7. Electronic pricing error. One item at no cost. Signage

(a) In the event that any consumer commodity electronically scans at the cash register or checkout terminal at a retail price which is higher than the posted retail price, one item of such consumer commodity, up to a value of twenty dollars, shall be given to the consumer at no cost.

(b) The consumer shall be informed of the retailer's obligation to provide one item free up to a value of twenty dollars, by means of the conspicuous sign referred to in section 21a-79-6 (a) of the Regulations of Connecticut State Agencies or section 21a-79 of the Connecticut General Statutes, and a second conspicuous sign attached to each cash register or checkout terminal in a retailer's establishment. The sign attached to the cash register or checkout terminal shall be at least six inches by eight inches in size, easily readable by a consumer making a purchase at such cash register or checkout terminal, and shall not contain any additional text including but not limited to store or promotional slogans, names, or advertising, other than that required by section 21a-79 (b) 6 of the Connecticut General Statutes. As an alternative to such cash register or checkout terminal signs, the retailer may display a conspicuous sign, with minimum dimensions of 22 inches by 28 inches, at each public entrance within the store, which sign shall not contain any store or promotional slogans, names, or advertising and which shall read, in clear and conspicuous type, as follows:

“In the event that a consumer commodity scans at a higher price, you will be given one item of that consumer commodity free of charge up to a value of \$20.00. Credit will be given for items of higher value.”

(Effective October 25, 1993; Amended October 1, 2007)

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Subject

Plumbing Fixtures

Inclusive Sections

§§ 21a-86a-1—21a-86a-6

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Plumbing Fixtures

Sec. 21a-86a-1. Definitions

As used in these regulations, the following terms shall, unless the context requires otherwise, have the following meanings:

- (a) “ANSI” means the American National Standards Institute;
- (b) “Commissioner” means the Commissioner of the Department of Consumer Protection;
- (c) “Building Inspector” means a state or local official whose function it is to inspect and approve new building construction and building renovation;
- (d) “Plumbing fixtures” means water closets, including tank-type toilets, flushometer-tank toilets, flushometer-valve toilets, electromechanical hydraulic toilets and any other toilet that uses water; urinals; replacement aerators; showerheads; lavatory, kitchen and bathroom sink faucets; and specifically includes floor models and demonstration units; and
- (e) A “store” means a place where merchandise is kept and offered for sale.

(Effective June 22, 1990)

Sec. 21a-86a-2. Efficiency standards

(a) This section pertains to showerheads, urinals, replacement aerators, bathroom, lavatory, and kitchen faucets, and any toilet that uses water.

(1) The manufacturer shall test samples of each model of covered plumbing fixtures to be sold at retail in Connecticut. Such testing shall occur at a laboratory to be approved by the Commissioner, and in accordance with the state building code.

(2) To be approved by the Commissioner, a laboratory shall complete and submit a Laboratory Certification Form from the Commissioner.

(b) The maximum flow rate for all new showerheads shall be 2.5 gallons per minute.

(1) All showerheads equipped with flow restrictors mechanically retained at the point of manufacture shall be tested with the restrictor in place. Mechanically retained shall mean that the insert cannot be shaken out of the showerhead, but would require a force of at least eight pounds to remove the insert.

(2) Showerheads with a radially drilled hole which is sealed when the flow restricting mechanism is in position, but which sprays water out of the side of the showerhead when the flow restricting mechanism is removed, shall also be tested with the flow restricting mechanism in place. Showerheads in which a flow restricting mechanism is not mechanically retained at the point of manufacture shall be tested with the flow restricting mechanism removed.

(c) The maximum water use for urinals shall be 1.0 gallons per flush.

(d) The maximum flow rate for replacement aerators shall be 2.5 gallons per minute.

(e) The maximum flow rate for bathroom sink, lavatory and kitchen faucets shall be 2.5 gallons per minute.

(f) Lavatories in restrooms or public facilities shall be equipped with outlet devices which limit the flow rate to 0.5 gallon per minute.

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(g) The maximum water use for water closets, tank-type toilets, flushometer-tank toilets, flushometer-valve toilets, electromechanical hydraulic toilets and any other toilet that uses water shall be 1.6 gallons per flush unless and until equivalent standards for similar types of toilets are adopted by ANSI.

(Effective June 22, 1990)

Sec. 21a-86a-3. Certification

(a) No person may sell, offer for sale or install any new showerhead, urinal, faucet or replacement aerator on and after October 1, 1990, or any new tank-type toilet, flushometer-tank toilet, flushometer-valve toilet, electromechanical hydraulic toilet or any other toilet that uses water on and after January 1, 1992 unless such showerhead, urinal, faucet, replacement aerator, tank-type toilet, flushometer-tank toilet, flushometer-valve toilet, electromechanical hydraulic toilet or any other toilet that uses water meets or exceeds the efficiency standards set forth in subsections (b) through (g) of Section 2 of these regulations, or is authorized under the conditions stated in subsection (b) of Section 3 of these regulations. The requirements of this section do not apply to the sale of plumbing fixtures which are to be sold or installed outside Connecticut.

(b) The sale of plumbing fixtures which do not meet the standards cited in subsections (b) through (g) of Section 2 of these regulations, such as those used for historical renovation or those which have technical problems, may be authorized if the Commissioner determines that compliance is not feasible or an unnecessary hardship exists. The Commissioner may also authorize the sale of plumbing fixtures, including, but not limited to, antique reproduction plumbing fixtures, which do not meet the standards, provided such plumbing fixtures were in stock in a store located in the state before October 1, 1990, for showerheads, urinals, faucets or replacement aerators; or before January 1, 1992 for tank-type toilets, flushometer-tank toilets, flushometer-valve toilets, or electromechanical hydraulic toilets.

(c) The manufacturer shall submit to the Commissioner a certification statement listing all new plumbing fixtures covered by these regulations. The certification statement shall contain the following information:

- (1) Name and address of manufacturer;
- (2) Type of plumbing fixture;
- (3) Brand name;
- (4) Model number;
- (5) Name of laboratory where tested; and
- (6) Maximum flow or use rate.

(d) Every certification statement submitted pursuant to this section shall be dated and signed by the manufacturer or third party acting on its behalf attesting to its truth and accuracy under penalty of perjury. When the manufacturer or third party is either a corporation or business association, the certification statement shall be dated and signed by an officer thereof. Each certification statement shall contain a declaration that the model(s) complies with the provisions of this section of these regulations.

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(e) Within 45 days after receipt of a certification statement, the Commissioner shall forward to the manufacturer or third party, if applicable, an acknowledgement that the statement has been received and whether or not it is complete.

(f) The results for all tests performed for certification of units pursuant to this Section shall be retained by the manufacturer for a period of two years following the model's certification. This requirement shall include the test results of models no longer being manufactured.

(g) The Commissioner or his/her authorized representative may request a copy of the test results from which the certification information for any model was derived, the name and address of the lab where the test was performed, and the date of the test. Failure to provide this information within 45 days shall result in the suspension of the model's certification.

(h) A third party may act on behalf of a manufacturer to certify a fixture. If a manufacturer allows a third party to act on its behalf, the third party shall submit with its certification statement a signed and dated statement authorizing it to act on behalf of the manufacturer. The manufacturer remains responsible for compliance with the provisions of these regulations notwithstanding any such use of an authorized third party. Additionally, the manufacturer is liable for any claims made on its behalf by an authorized third party.

(Effective June 22, 1990)

Sec. 21a-86a-4. Identification of complying plumbing fixtures

(a) Sufficient information shall be shown on the outside of the shipping carton for any fixture described in these regulations to permit the determination of whether the fixture complies with the requirements of these regulations. The appropriate measure of water use/flow rate or the model number as it has been certified may be used for this purpose and shall be deemed as providing sufficient information to determine compliance. Additionally, the actual tested flow/use rate, or other conspicuous marking approved by the Commissioner, shall be marked on each fixture sold or offered for sale at retail, either by means of a permanent marking on the fitting or on a label attached to the fitting and also on the unit carton in which the fitting is offered for retail sale.

(b) The Commissioner or his/her representative may require additional information if necessary to permit determination of compliance.

(c) The manufacturer's name or brand name shall appear on each fixture.

(Effective June 22, 1990)

Sec. 21a-86a-5. Enforcement

(a) Notwithstanding the provisions of Section 3 of these regulations, the Commissioner shall have authority to challenge the test results provided by the manufacturer and cause the fixture model to be retested.

(b) The Commissioner shall cause periodic inspections to be made of distributors or retailers of the new fixtures covered by these regulations.

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(c) The Commissioner of Consumer Protection or his/her representative shall have access at all reasonable times to places where distributors or retailers sell, store or maintain plumbing fixtures. Such access shall be for the purpose of making periodic inspections to determine compliance with the standards adopted pursuant to Section 2 of these regulations.

(d) Except as expressly provided herein, any test ordered by the Commissioner would involve one unit selected by the Commissioner's representative.

(1) If the performance of the unit meets or exceeds the standard set forth in Section 2 of these regulations, no further action is necessary, and the Department of Consumer Protection will pay the cost of testing.

(2) If the performance of the unit does not meet or exceed the standard set forth in Section 2 of these regulations, the manufacturer must pay the cost of testing and take whatever steps are necessary to recertify the fixture at a use/flow rate equal to or exceeding the standard. Further, the manufacturer shall provide information to the satisfaction of the Commissioner that, in the initial certification of the model, the value certified was determined in conformance with the requirements of Section 2 of these regulations.

Even if this information is provided, the manufacturer shall be required, at its own expense, to test up to two additional units selected by the Commissioner, in a laboratory acceptable to the Commissioner.

If the performance of the first of the two additional units meets or exceeds the standard set forth in Section 2 of these regulations, the second unit shall be tested. If the second unit meets or exceeds the standard, no further action shall be taken and the model shall retain its certification. If the performance of either the first or the second unit does not meet or exceed said standard, the certification for that model shall be suspended by the Commissioner's order. The results of these retests shall be provided to the Commissioner or his/her representative as a condition for recertation.

(3) If the certification for a model is suspended, the manufacturer may retest and recertify the model at its expense in a laboratory acceptable to the Commissioner or his/her representative.

(4) All test results and statistical calculations shall be provided to the Commissioner's representative. A determination of noncompliance shall result in the model's certification being suspended by the Commissioner's order. The model may not be recertified.

(5) If any of the tests of units required by the Commissioner pursuant to this subsection are not undertaken by a manufacturer, the certification for that model shall be suspended by the Commissioner's order.

(6) The Commissioner shall cause investigations to be made of complaints received concerning violations of Public Act 89-303. All such complaints shall identify the complainant by name and address and shall be in writing. The result of each investigation shall be reported to the attorney general.

(7) If the Commissioner finds that a violation of Public Act 89-303 has occurred, the violator shall be subject to a civil penalty of two hundred fifty dollars for each violation. Each violation shall be considered a separate offense and each day that such violation

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continues shall also be considered a separate offense.

(Effective June 22, 1990)

Sec. 21a-86a-6. Conflicting regulations and distribution

(a) In the event of any conflict between the efficiency standards for plumbing fixtures adopted pursuant to these regulations and the state building code adopted pursuant to section 29-252 of the general statutes, the more stringent regulations shall take precedence.

(b) The Commissioner shall distribute copies of these regulations to the Commissioner of Public Safety. In addition, the Commissioner shall notify state and local building inspectors of substandard models approved for sale pursuant to subsection (b) of Section 3 of these regulations.

(Effective June 22, 1990)

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Subject

Labeling of Cuts of Meat Sold by Food Establishments

Inclusive Sections

§§ 21a-100-1—21a-100-10

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Labeling of Cuts of Meat Sold by Food Establishments

Sec. 21a-100-1. Statement of purpose

The purpose of these regulations is to establish a set standard of descriptive terms to be applied to the various cuts of meat. Food establishments shall be required to use these uniform terms in the labeling and advertising of all meat and meat food products offered for sale therein.

(Effective June 22, 1990)

Sec. 21a-100-2. General definitions

(a) “Commissioner” as used in these regulations means the Commissioner of Consumer Protection.

(b) “Food Establishment” means an establishment in which food is stored, processed, prepared, offered for sale, or sold directly to the consumer.

(c) “Inspector” means an employee or official of the Department of Consumer Protection authorized by the Commissioner.

(d) “Meat” means the edible part of the muscle of cattle, swine, or sheep which is skeletal or which is found in the tongue, in the diaphragm, in the heart, or in the esophagus, with or without the accompanying of overlying fat and portions of skin, bone, nerve, and blood vessels which normally accompany the muscle tissue and which are separated from it in the process of dressing. It does not include the muscle found in the lips, snout, or ears.

(e) “Meat food product” means any product capable of use as food which is made wholly or part from any meat or other portion of the carcass of any cattle, sheep, swine, or goats, excepting products which contain meat or other portions of such carcasses only in a relatively small proportion or historically have not been considered by consumers as products of the meat food industry, and which are exempted from definition as a meat food product by the Commissioner under such conditions as he may prescribe to assure that the meat or other portions of such carcasses contained in such product are not adulterated and that such products are not represented as meat food products.

(f) “Operator” means any person who (i) alone or jointly or severally with others owns a food establishment, or (ii) has care, charge or control of a food establishment as agent or manager for the owner or as an independent contractor.

(Effective June 22, 1990)

Sec. 21a-100-3. Fanciful names and true names for cuts of meat

(a) “Fanciful name” refers to any term used in connection with a particular cut of meat, which is in any way false, misleading, deceptive, or confusing, or which otherwise fails to adequately describe the cut of meat.

(b) “True name” means the species of animal i.e, beef, veal, lamb or pork, and the primal source or area of the animal carcass from which the meat is derived and shall consist of one, but not more than one, of the following:

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(1) For beef: cheeks, tongue, gullets or esophagus, shoulder, chuck, heart, brisket, shank, shin, rib, plate, diaphragm, loin, flank, rump, top round or bottom round.

As used in relation to beef herein and as set forth in Chart #1 attached hereto:

“Neck” is derived from the area of the chuck containing atlas bone through the fifth cervical vertebra.

“Shoulder” is derived from the area of the chuck which includes clod, forearm, brisket muscle and arm bone and may include cross sections of the ribs.

“Brisket” is derived from the area of the chuck which includes part of ribs 1 through 5 and the sternum (breast bone).

“Foreshank” is derived from the upper portion of the fore leg and contains the upper shank bone.

“Chuck” is derived from that area of the forequarter containing ribs 1 through 5 without neck, brisket, and foreshank.

“Diaphragm” is derived from the forequarter and includes the muscles and tendon attachments which separate the thoracic (chest) cavity from the abdominal cavity.

“Rib” is derived from the forequarter and includes the 6th through the 12th ribs after removal of the plate approximately 10 inches from the chime bone.

“Plate” is derived from the forequarter and includes the 6th through the 12th ribs cut approximately 10 inches from the chime bone.

“Hind shank” is derived by cutting through the stifle joint severing the shank meat and the shank bone from the round.

“Round” is separated from the full beef loin by a straight cut which starts at a point on the backbone at the juncture of the last (5th) sacral vertebra and the first tail (caudal) vertebra, passes through a second point which is immediately anterior to the protuberance of the femur bone and exposes the ball of the femur, and then continues in the same straight line beyond this second point to complete the cut.

“Rump” is derived from the round and is removed therefrom by a straight cut perpendicular to the outer skin surface immediately posterior to, and parallel with the long axis of the exposed surface of the aitch bone.

“Loin” is located between the rib and the round and is removed by a cut between the 12th and 13th ribs (posterior end of the rib) and contains the 13th rib vertebra, six lumbar vertebrae and five sacral vertebrae.

“Sirloin” is derived from the loin of cattle by a straight cut made perpendicular to the contour of the outer surface and perpendicular to the split surface of the lumbar vertebrae and passes flush with the ilium (pelvic bone) leaving a small part of the hip bone in the short loin.

“Short loin” is the anterior portion of the loin remaining after the removal of the posterior portion (sirloin) of the loin and is obtained by a straight cut perpendicular to the contour of the outer surface and perpendicular to the split surface of the lumbar vertebrae and which passes through the ilium (pelvic bone) leaving a small piece of the hip bone in the short loin.

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“Flank” is derived by stripping the serous membrane from over the abdomines muscles (flank steak) and by pulling the abdomines muscle from the thick membrane which lies underneath.

(2) For veal - cheeks, tongue, gullets, or esophagus, heart, neck, shank, breast, shoulder, rib, loin, sirloin, rump or leg.

As used in relation to veal herein and as set forth in Chart #2 herein:

“Neck” is derived from the shoulder by a straight line cut in front of the blade bone approximately between the 4th and 5th cervical vertebrae and parallel to the rib end of the shoulder.

“Shank” is derived from the leg bone (tibia) or the arm bone (radius).

“Breast” is derived by a cut perpendicular to the outer surface which passes through the cartilaginous juncture of the first rib and anterior extremity of the sternum and perpendicular to the long axis of the 12th rib approximately 4 inches from the eye of rib, and contains the sternum, first twelve ribs and all overlaying muscle, except the foreshank.

“Shoulder” is the section remaining after removal of the foreshank, breast and neck and contains the 1st through the 5th ribs.

“Rib” is removed from the shoulder by cutting between the 5th and 6th ribs and contains featherbone, chime bone and rib bones.

“Loin” is located between the sirloin and rib and is removed from the rib by a cut between the 12th and 13th ribs and from the sirloin by a cut perpendicular to the outer surface immediately anterior to and flush with the ilium (pelvic bone) leaving no part of the hip bone in the loin and includes the 13th rib vertebra and 5 lumbar vertebrae.

“Leg” is removed from the sirloin and rump by a straight line cut perpendicular to the outer skin surface immediately posterior to and parallel with the long axis of the exposed surface of the aitch bone, leaving no part of the aitch bone in the leg. The separation of the sirloin and rump from the leg is completed by sawing through the round bone (femur) immediately posterior to the ball joint.

“Rump” is removed from the leg as aforesaid and is removed from the loin by a cut perpendicular to the outer skin surface and perpendicular to the backbone at the anterior end of the hip bone leaving all the hip bone in the rump.

“Sirloin” is derived from the anterior end of the rump by a cut perpendicular to the dorsal side starting at any point on the backbone between the juncture of the last (5th) sacral vertebra and the anterior end of the ilium (pelvic bone) or between the 5th and 6th lumbar vertebrae.

(3) For lamb - cheeks, tongue, gullets or esophagus, heart, neck, shank, breast, shoulder, rib, loin or leg.

As used in relation to lamb herein and as set forth in Chart #3 herein:

“Neck” is derived from the anterior area of the shoulder and contains the atlas and cervical vertebrae.

“Breast” is cut from the loin, neck, and shoulder, starting at the cod or udder to and through the shank just above the elbow.

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“Shoulder” is separated from the ribs by cutting between the 5th and 6th ribs.

“Rib” is separated from the loin by cutting between the last two ribs.

“Loin” is separated from the leg by cutting just in front of the hip bone.

“Leg” is the portion remaining after the loin has been removed as aforesaid.

(4) For pork - cheeks, tongue, gullets or esophagus, heart, tail, jowl, shoulder, shoulder picnic, shoulder butt, feet, side, spareribs, loin, loin-shoulder end or loin-rib end, loin-center cut, loin-loin end, fat back or ham.

As used in relation to pork herein and as set forth in Chart #4 herein:

“Jowl” shall be removed closely to the body of the shoulder on a line approximately parallel to the opposite straight cut side of the shoulder, starting behind the “ear dip” which must remain on the jowl and continuing the cut so as to remove the entire jowl.

“Shoulder” is derived by a cut starting at a point in the armpit that is not more than 1 inch posterior to the elbow joint, but does not expose the elbow joint, and continues reasonably straight across the hogside. The foot, ribs and related cartilages, breast bone, intercostal meat, breast flap, and neck bones shall be excluded.

“Shoulder picnic” is separated from the shoulder butt by a cut which is reasonably straight and perpendicular to the outside skin surface (not slanted or under cut) and approximately parallel to the breast side of the shoulder leaving all the major shoulder bone (humerus) and not less than one nor more than two inches of the blade bone (scapula) in the shoulder picnic.

“Side (Belly)” shall be separated from the fat back on a straight line not more than $\frac{3}{4}$ inch beyond the outermost curvature of the scribe line. The belly must be boneless and the major cartilages of the sternum and the ribs must be closely and smoothly removed without deep scoring. Any enlarged soft, porous, or seedy mammary tissue and the pizzle recess of barrow bellies must be removed.

“Loin” is removed from the middle portion by a cut (scribe) extending from a point on the first rib of the loin which is not more than $1\frac{3}{4}$ inches from the junction of the foremost rib and the foremost thoracic vertebra to a point on the ham end which is immediately adjacent to the major tenderloin muscle. The loin shall be removed from the fat back and shall contain 11 or more ribs, 7 lumbar vertebrae and at least 3 sacral vertebrae.

“Loin-shoulder end” (Loin-rib end) is derived from the pork loin by a cut perpendicular to the length of the loin flush with the posterior edge of the blade bone.

“Loin-center cut” is derived from the pork after the shoulder end has been removed by cutting crosswise to the length of the loin at a point posterior to the edge of the scapular cartilage and from which the ham end of the loin has been removed by cutting crosswise to its length anterior to the cartilage on the tuber coxae.

“Loin-loin end” is derived from the pork loin by a cut perpendicular to the length of the loin flush with the anterior end of the ilium leaving no part of the hip bone in the loin.

“Fat back” is the section remaining after removal of the loin and side.

“Ham” is the posterior portion of the hog side removed by a cut $2\frac{1}{4}$ to $2\frac{3}{4}$ inches anterior to the knob end of the aitch bone. The cut shall be at right angles to an imaginary line from the top of the aitch bone through the center of the ham and shank. At the flank pocket the

cut shall divert at a 45° angle posteriorly.

(Effective June 22, 1990)

Sec. 21a-100-4. Standard descriptive terms for certain cuts of meat

(a) “Bacon” means cured and smoked meat, either sliced or slab, taken from the side of a swine carcass.

(b) “Club steak” means meat derived from the anterior end (rib end) of the short loin of cattle or the posterior end (loin end) of the rib. Any labeling or advertising for “Club Steak” shall indicate short loin or rib, whichever is appropriate. “Club Steak” may be specified to be either bone-in or boneless.

(c) “Filet Mignon” means meat derived from the tenderloin (psoas muscle) of cattle.

(d) “Ground beef,” “Ground veal,” “Ground lamb,” or “Ground pork,” means ground, fresh or frozen meat other than from the heart, esophagus, tongue or cheeks of the species indicated, without the addition of fat as such. The ground meat shall not contain more than 30% of fat and shall not contain water, binders, or extenders.

(1) Ground beef identified as “lean ground beef” or “lean chopped beef” shall contain not more than 22% fat.

(2) Ground beef identified as “extra lean ground beef” or “extra lean chopped beef” shall contain not more than 15% fat.

(3) Ground beef identified as “diet lean ground beef” or “diet lean chopped beef” shall contain not more than 10% fat and shall state the maximum percentage (%) of fat contained in the ground beef or chopped beef on the label adjacent to and of the same type size as the product identity.

(e) “Ground chuck” means ground fresh or frozen beef, derived from the chuck, which shall not contain more than 20% fat and shall not contain added water, binders, or extenders and shall state the maximum percentage (%) of fat contained in the ground chuck on the label adjacent to and of the same type size as the product identity.

(f) “Ground round” means ground fresh or frozen beef, derived from the round, which shall not contain more than 15% fat and shall not contain added water, binders, or extenders and shall state the maximum percentage (%) of fat contained in the ground round on the label adjacent to and of the same type size as the product identity.

(g) “Ground sirloin” means ground fresh or frozen beef, derived from the sirloin, which shall not contain more than 13% fat and shall not contain added water, binders, or extenders and shall state the maximum percentage (%) of fat contained in the ground sirloin on the label adjacent to and of the same type size as the product identity.

(h) “Hamburger” means chopped or ground fresh or frozen beef, other than from the heart, esophagus, tongue, or cheeks, with or without the addition of beef fat as such and shall not contain added water, binders or extenders. “Hamburger” shall not be composed of more than 30% fat.

(1) Hamburger identified as “lean hamburger” shall contain not more than 22% fat.

(2) Hamburger identified as “extra lean hamburger” shall contain not more than 15%

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fat.

(3) Hamburger identified as “diet lean hamburger” shall contain not more than 10% fat and shall state the maximum percentage (%) of fat contained in theburger on the label adjacent to and of the same type size as the product identity.

(i) “Porterhouse steak” means meat derived from the short loin of cattle and which exhibits not less than 1 1/4 inches in diameter of tenderloin (psoas muscle).

(j) “Sirloin steak” means meat derived from the posterior portion of the loin of cattle after the removal of the short loin. “Sirloin steak” may be specified to be either with or without tenderloin.

(k) “Sirloin knuckle or sirloin tip” means meat derived from the beef round by a straight cut from the knee cap parallel to and along the femur on the inside of the round and the natural seam of the outside of the round.

(l) “Skirt steak” means meat derived from the diaphragm of cattle.

(m) “Spare ribs” means ribs which are removed from the belly portion of the pork carcass mid-section extending from the scribe line at the fat back side of the belly to and including portions of the rib cartilages, with or without a portion of the split breast bone and with or without the skirt (diaphragm) remaining.

(n) “Stew beef” means meat, other than from the heart, esophagus, tongue or cheeks, which is derived from cattle and which is commonly used for stewing.

(o) “Strip loin steak” means meat derived from that portion of the short loin of cattle remaining after the tenderloin (psoas muscle) has been removed.

(p) “T-bone steak” means meat derived from short loin of cattle which exhibits not less than ½ inch diameter of the psoas muscle.

(q) “Tenderloin” means meat derived from the psoas muscle of cattle, swine or sheep.

(r) “Top sirloin butt” means meat derived from the posterior portion of the loin of cattle after removal of the short loin and which is the thick upper portion (dorsal side) of the sirloin after removal of the bottom sirloin (ventral side) by a cut following the natural muscle seam (blue tissue).

(s) “Bottom sirloin butt” means meat derived from the posterior portion of the loin of cattle after removal of the short loin and which is the lower portion (ventral side) of the sirloin after removal of the top sirloin butt (dorsal side) by a cut following the natural muscle seam (blue tissue).

(t) “Veal cutlet” means a single slice of veal taken from the round. The thickness of the slice may vary, but the combining of slices is not permitted when the term “veal cutlet” is used.

(Effective June 22, 1990)

Sec. 21a-100-5. Labeling requirements

(a) No food establishment shall produce, prepare, package, advertise, sell, or offer for sale any meat unless it is clearly and conspicuously labeled or advertised as the case may be, as to its true name. The labeling or advertising shall also state whether the product is

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boneless or whether it has the bone-in.

(b) Fanciful names, such as “His and Her Steak,” “Chicken Steak,” and “Chicken Roast,” are prohibited.

(c) A name in addition to the true name may be used, provided that such name is not false, misleading, deceptive, or confusing in any way. Any such additional name shall appropriately describe the cut of meat to which it refers or the use to which such cut is put or its method of preparation. Examples of permissible additional names include “Pot Roast,” “Oven Roast,” “Delmonico Steak,” “Cube Steak,” “Sandwich Steak,” “Steak for Swissing,” and “Beef Chuck for London Broil.”

(d) Whenever a name in addition to the true name is used, the true name shall appear contiguous to the additional name in at least the same size of type and style of lettering and on the same background as the additional name. For example:

SANDWICH STEAK - BEEF ROUND

(e) Whenever a name in addition to the true name is used orally in a radio or television advertisement, an immediate reference shall be made to the true name of the cut of meat being advertised.

(f) The true name need not be included in the labeling or advertising of bacon, club steaks, Delmonico steaks, filet mignon, and other cuts of meat specifically defined in Section IV of these regulations, provided that, the meat is clearly and conspicuously labeled or advertised as to its name as defined in these regulations.

(g) Meat food products, such as chili con carne, hash, meat stews, spaghetti sauces, deviled ham, bologna, and frankfurters, need not be identified with their true name, provided that, in the case of any of these products, it complies with the labeling standards prescribed in Section XV of the Connecticut Meat and Poultry Products Inspection Act.

(h) Grading terms may not be used in the labeling or advertising of meat unless the carcass or part thereof from which such meat is derived has been so marked by the U.S. Department of Agriculture. No qualifying words may be used with an official U.S. grade. Grading terms, such as “prime” or “choice,” shall not be used in the labeling or advertising of pork.

(i) If a grading term other than “prime” or “choice” is used in labeling or advertising meat, the grading term used must appear contiguous to the true name of such meat and be at least equal in size and as prominent as the true name. “Packer graded” meat shall be so described if the packer name is used to indicate grade or quality.

(j) Qualifying statements, such as “water-added” or “chopped, shaped and cubed,” shall be contiguous to the product name, not less than two-thirds of the size, and in the same style type as the product name.

(k) The term “larding” or “fat added” means the addition of fat in a uniform layer not more than $\frac{1}{4}$ inch in thickness surrounding the exterior of a roast with a thickness of not more than $\frac{1}{4}$ inch of fat in any portion thereof. If a piece of meat is larded, it shall contain the name thereof, the true name of the meat with the words “fat added” contiguous to the true name and not less than $\frac{2}{3}$ of the size in the same style lettering as the true name. The

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fat shall be fat from the same species of animal as the meat to which it is added.

(l) The term “steak” when used in conjunction with meat shall mean the whole portion of meat as removed from the carcass. Ground or chopped meat shall not be labeled as steak.

(m) The term “hanging tender” means meat derived from the thick muscular dorsal attachment (pillar) of the diaphragm of cattle. Whenever such meat is labeled or advertised for sale at retail, the term “hanging tender” and only such term shall be used in said labeling or advertising and then only if used in conjunction with the term “pillar of diaphragm.”

(n) For pork chops, the true name shall consist of one of the following primal sources: shoulder or blade, rib, loin, center, or loin end or sirloin. When a quarter loin is cut into chops and sold in a combination pack or family pack, the label shall specify the number of center cut pork chops and the number of end cut pork chops included in the package.

(Effective June 22, 1990)

Sec. 21a-100-6. Administrative provisions

(a) These regulations shall apply to any meat which is produced, prepared, packaged, advertised, sold, or offered for sale, whether packaged or unpackaged, which is identified or named in any way, whether it be by labeling, advertising, or any other means.

(b) All food establishments within this state shall be subject to periodic investigations by inspectors duly authorized by the Commissioner.

(c) Any meat or meat food product failing to meet the labeling requirements of these regulations is “misbranded” within the meaning of the Uniform Food, Drug, and Cosmetic Act, Section 21a-102 of the Connecticut General Statutes. Such misbranding constitutes a prohibited act under Section 21a-93 and subjects the operator of the food establishment selling such meat or meat food products to the penalties enumerated in Section 21a-95.

(d) The use in radio, television, newspaper or other advertising of a name in addition to the true name of a particular cut of meat without an immediate reference to the true name shall constitute a false and misleading advertisement within the meaning of Section 21a-113 of the Connecticut General Statutes. The dissemination of such false and misleading advertisement is a prohibited act under Section 21a-93 (e). The violation of Section 21a-93 (e) shall subject the operator to the penalties prescribed in Section 21a-95.

(e) Before any such penalty is imposed, the operator shall be given the opportunity to request a hearing before the Commissioner to be conducted pursuant to the provisions of the Administrative Procedure Act, Chapter 54 of the Connecticut General Statutes.

(f) Nothing herein shall be construed as requiring the Commissioner to initiate proceedings against an operator allegedly guilty of a minor violation of these regulations. A written notice or warning to the operator may be sufficient whenever the Commissioner feels that the public interest will be adequately served thereby. A continuing violation, or second or subsequent offense, will subject the operator to the full penalties prescribed in the Uniform Food, Drug, and Cosmetic Act.

(g) Exemptions from the labeling requirements contained in these regulations may be granted at the discretion of the Commissioner for special cuts of meat intended for a

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particular ethnic group. Retailers desiring such exemptions shall submit a written request for exemptions to the Commissioner.

(h) In order to allow a sufficient period of time for any necessary changes in printing procedures, retail food establishments shall have 60 days from the effective date of these regulations in which to implement the new labeling requirements.

(i) These regulations shall not apply to any meat which is produced, prepared, or packaged for sale within this state under the procedures prescribed by the U.S. Department of Agriculture until after such meat leaves the premises of a U.S.D.A. official establishment for distribution.

(j) These regulations shall not apply to meat which is produced, prepared, or packaged under the procedures prescribed by the U.S. Department of Agriculture for sale at retail outside the State of Connecticut.

(See Charts 1, 2, 3 and 4 on following pages.)

(Effective June 22, 1990)

Standards of Identity for Olive Oil

Sec. 21a-100-7. Statement of purpose and scope

This standard applies to olive oil and olive-pomace oil presented and sold for human consumption in intrastate commerce in the state of Connecticut.

(Adopted effective November 5, 2008)

Sec. 21a-100-8. General definitions

As used in sections 21a-100-7 to 21a-100-10, inclusive of the Regulations of Connecticut State Agencies:

(1) "IOC" means the International Olive Council, an international voluntary consensus trade organization formed for the development of standards on characteristics and performance of olive products and the promotion of trade and knowledge related to the accurate and honest presentation of such products.

(2) "Olive oil" means the olive oil obtained solely from the fruit of the olive tree (*Olea Europaea* L.), to the exclusion of oils obtained using solvents or re-esterification processes and of any mixture with oils of other kinds.

(3) "Olive oil," for the purpose of product labeling, means oil consisting of a blend of refined olive oil, and virgin olive oils fit for consumption as they are. It has a free acidity, expressed as oleic acid, of not more than 1 gram per 100 grams and its other characteristics correspond to those fixed for this category in sections 21a-100-7 to 21a-100-10, inclusive, of the Regulations of Connecticut State Agencies.

(4) "Olive-pomace oil," for the purpose of product labeling, means oil obtained by treating olive pomace with solvents or other physical treatments, to the exclusion of oils obtained by re-esterification processes and of any mixture with oils of other kinds.

(5) "Refined olive oil," for the purpose of product labeling, means the olive oil obtained

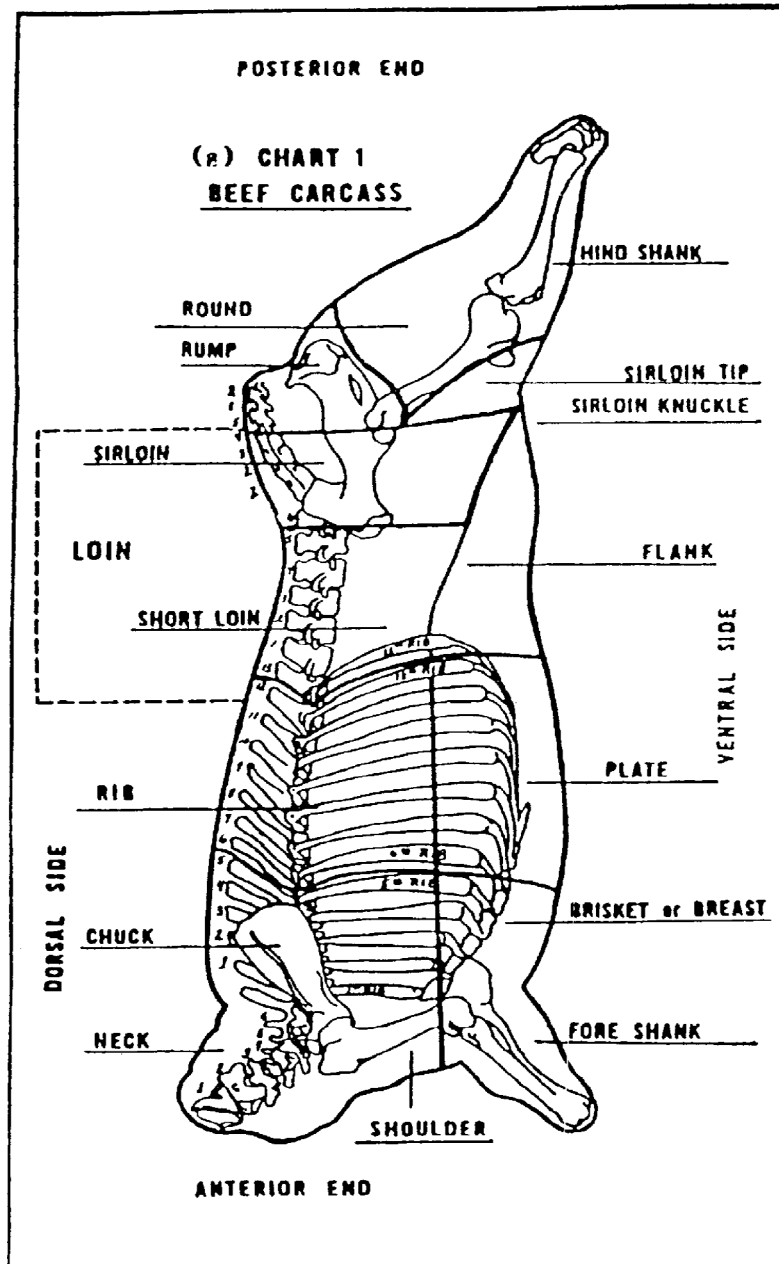
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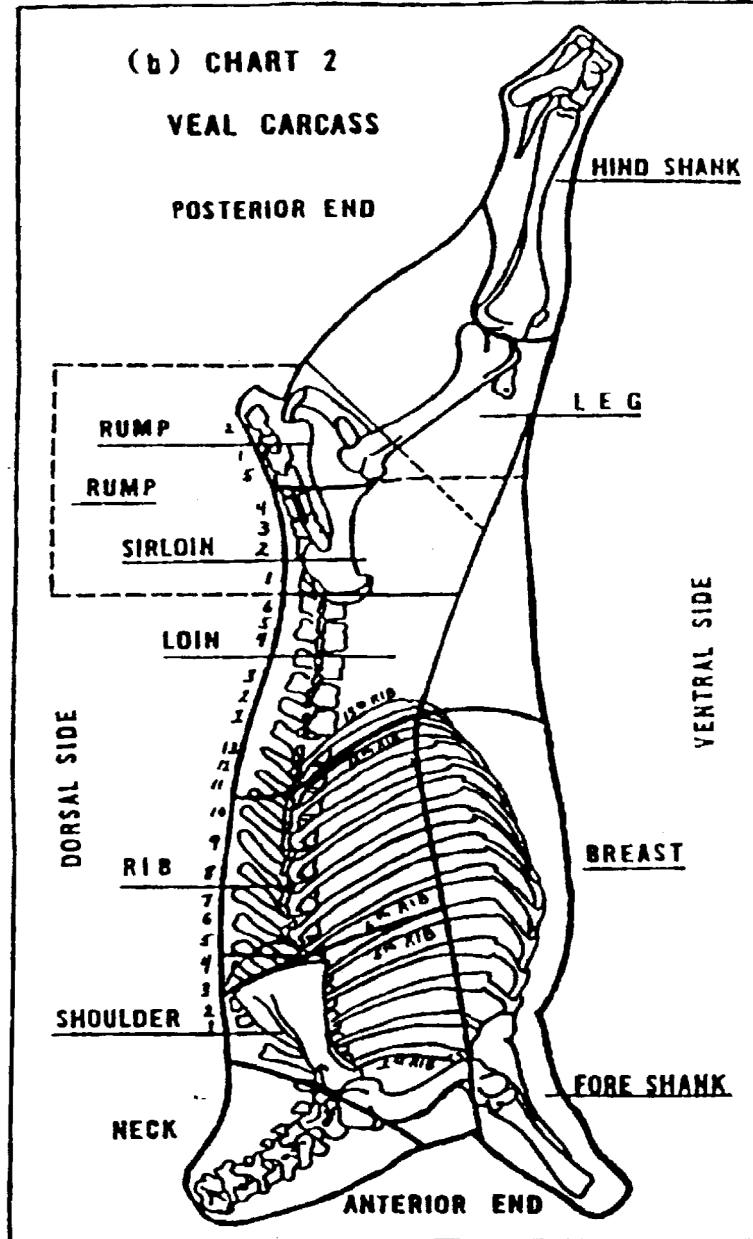
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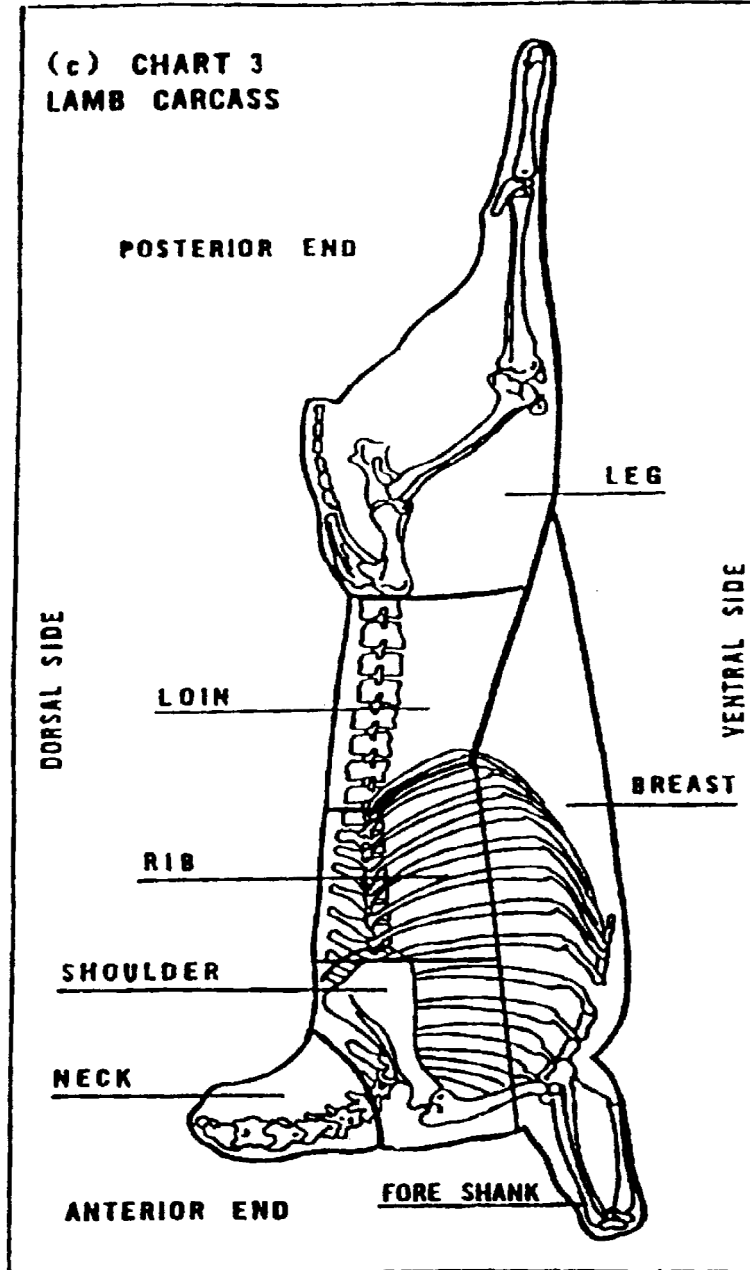
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from virgin olive oils by refining methods which do not lead to alterations in the initial glyceridic structure. It has a free acidity, expressed as oleic acid, of not more than 0.3 grams per 100 grams and its other characteristics correspond to those fixed for this category in sections 21a-100-7 to 21a-100-10, inclusive of the Regulations of Connecticut State Agencies.

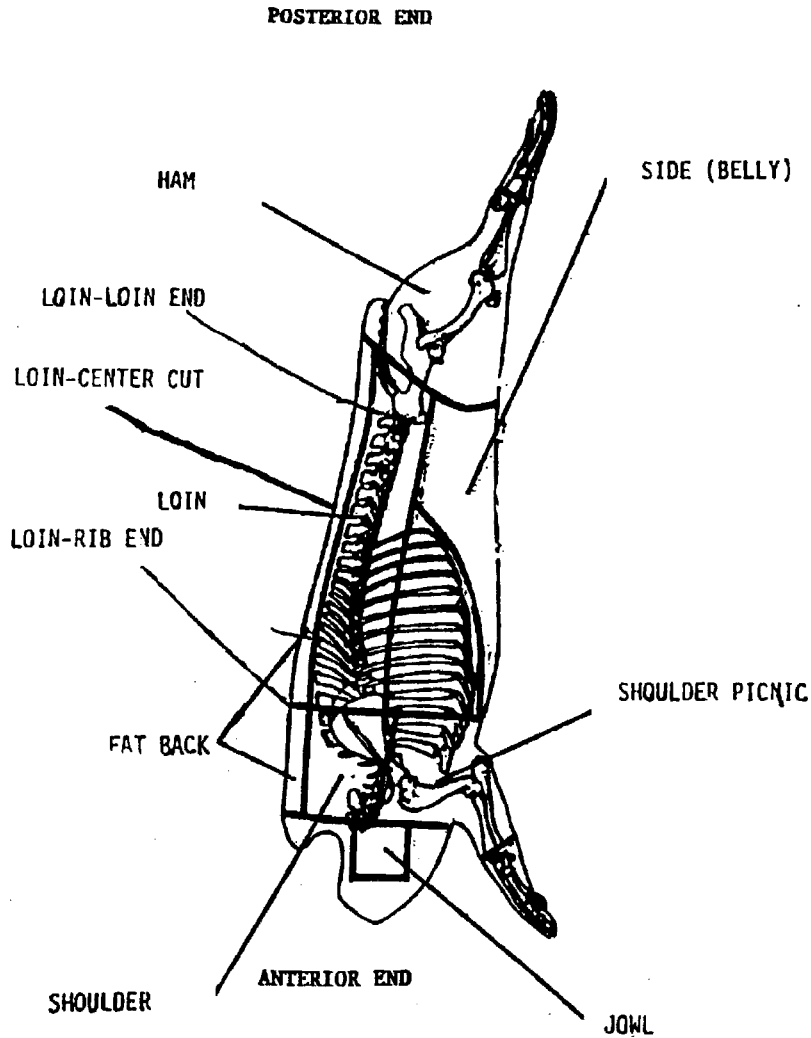






(d) CHART 4

PORK CARCASS



(6) "Virgin olive oil," for the purpose of product labeling, means those oils obtained from the fruit of the olive tree solely by mechanical or other physical means under conditions, particularly thermal conditions, that do not lead to alterations in the oil, and which have not undergone any treatment other than washing, decanting, centrifuging and filtration. Virgin olive oils fit for consumption as they are include:

(A) "Extra virgin olive oil," which means virgin olive oil which has a free acidity, expressed as oleic acid, of not more than 0.8 grams per 100 grams, and the other

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characteristics of which correspond to those fixed for this category in sections 21a-100-7 to 21a-100-10, inclusive of the Regulations of Connecticut State Agencies.

(B) “Virgin olive oil,” which means virgin olive oil which has a free acidity, expressed as oleic acid, of not more than 2 grams per 100 grams and the other characteristics of which correspond to those fixed for this category in sections 21a-100-7 to 21a-100-10, inclusive of the Regulations of Connecticut State Agencies.

(C) “Ordinary virgin olive oil,” which means virgin olive oil which has a free acidity, expressed as oleic acid, of not more than 3.3 grams per 100 grams and the other characteristics of which correspond to those fixed for this category in sections 21a-100-7 to 21a-100-10, inclusive of the Regulations of Connecticut State Agencies.

(Adopted effective November 5, 2008)

Sec. 21a-100-9. Food additives

(a) **Virgin olive oils.** No additives are permitted in virgin olive oils.

(b) **Refined olive oil, olive oil, refined olive-pomace oil and olive-pomace oil.** The addition of alpha-tocopherol to such products is permitted to restore natural tocopherol lost in the refining process. The concentration of alpha-tocopherol in the final product shall not exceed 200 mg/kg.

(Adopted effective November 5, 2008)

Sec. 21a-100-10. Standards for olive oil, labeling and administrative provisions

(a) The Commissioner of Consumer Protection and the Director of The Connecticut Agricultural Experiment Station shall require that olive oil presented and sold for human consumption in intrastate commerce in the state of Connecticut shall meet the International Olive Council standards, COI/T.15/NC no.3/ Rev. 2, entitled “Trade Standard Applying to Olive Oils and Olive-Pomace Oils,” as amended from time to time, or the standard of identity for olive oil as adopted by the United States Food and Drug Administration when such standards have been adopted.

(b) A copy of the IOC trade standard applying to olive oils and olive-pomace oils shall be maintained by the department for examination by the public during normal business hours until such time that a standard of identity for olive oil has been adopted by the United States Food and Drug Administration.

(c) Failure to meet the standards required in subsection (a) of this section shall render olive oil sold in intrastate commerce in the state of Connecticut misbranded pursuant to Section 21a-102 of the Connecticut General Statutes.

(Adopted effective November 5, 2008)

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Sanitary Standards for Food Establishments

Sec. 21a-101-1. Statement of purpose

(a) The purpose of this section and sections 21a-101-2, 21a-101-7 and 21a-101-8 of the Regulations of Connecticut State Agencies is to provide definitive sanitary standards for food establishments. Section 21a-101 (a) (4) of the Connecticut General Statutes provides that a food shall be deemed to be adulterated if it has been produced, prepared, packed or held under unsanitary conditions whereby it may become contaminated with filth or whereby it may have been rendered diseased, unwholesome or injurious to health. A substantial failure to comply with said regulations shall constitute such unsanitary conditions.

(b) The United States Food and Drug Administration Food Code, as amended from time to time by the Conference for Food Protection, and published and adopted by the United States Food and Drug Administration and the United States Department of Health and Human Services, is adopted and herein incorporated by reference as the sanitary standards for this state.

(Effective June 22, 1990; Amended September 1, 2005; Amended October 11, 2016)

Sec. 21a-101-2. Definitions

Definitions promulgated under the United States Food and Drug Administration Food Code, as amended from time to time by the Conference for Food Protection, and published and adopted by the United States Food and Drug Administration, and the United States Department of Health and Human Services shall be the definitions for the purposes of section 21a-101-1, this section and sections 21a-101-7 and 21a-101-8 of the Regulations of Connecticut State Agencies with the following additions:

- (1) “Commissioner” means the Commissioner of Consumer Protection;
- (2) “Food Establishment” means any establishment in which food is stored, offered for sale, processed, or prepared, other than an eating or drinking establishment, and includes the transportation of any food;
- (3) “Inspector” means an employee or official of the Department of Consumer Protection authorized by the commissioner; and
- (4) “Operator” means any person who (i) alone or jointly or severally with others owns a food establishment, or (ii) has care, charge or control of a food establishment as agent or manager for the owner or as an independent contractor.

(Effective June 22, 1990; Amended September 1, 2005; Amended October 11, 2016)

Sec. 21a-101-3. Construction and maintenance (Repealed)

Repealed October 11, 2016.

(Effective June 22, 1990; Amended September 1, 2005; Repealed October 11, 2016)

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Sec. 21a-101-4. Equipment and utensils (Repealed)

Repealed October 11, 2016.

(Effective June 22, 1990; Amended September 1, 2005; Repealed October 11, 2016)

Sec. 21a-101-5. General sanitary requirements (Repealed)

Repealed October 11, 2016.

(Effective June 22, 1990; Amended September 1, 2005; Repealed October 11, 2016)

Sec. 21a-101-6. Cleanliness of personnel (Repealed)

Repealed October 11, 2016.

(Effective June 22, 1990; Amended September 1, 2005; Repealed October 11, 2016)

Sec. 21a-101-7. Source of food

(a) All food shall be from an approved source and shall be clean, wholesome, free from spoilage, decay, or misbranding, and safe for human consumption. All food products, while being stored, prepared, or transported, shall be handled so as to prevent their becoming contaminated with filth. Food shall be protected from cross contamination by separating raw animal foods by species and by separating raw animal foods from raw ready-to-eat foods and ready-to-eat foods.

(b) All food products shall meet the standards of identity established for such products under applicable federal and state regulations, codes, or statutes.

(c) All baked goods, frozen desserts, and non-alcoholic beverages manufactured or offered for sale in a food establishment shall have been manufactured or produced in a facility duly licensed by the Connecticut Department of Consumer Protection.

(d) All meat and meat products and all poultry and poultry products held or sold in food establishments shall have been inspected for wholesomeness under an official regulatory program. The temperature in meat storage rooms shall be 41 degrees Fahrenheit or lower. The temperature in meat cutting and wrapping rooms shall be maintained to ensure that the temperature of the meat shall be 45 degrees Fahrenheit or lower.

(Effective June 22, 1990; Amended September 1, 2005; Amended October 11, 2016)

Sec. 21a-101-8. Administrative provisions

(a) All food establishments within this state shall be subject to periodic investigations by inspectors duly authorized by the commissioner. Following the completion of an investigation, the inspector shall file a written report of his findings. A copy of this report shall be left with the operator or an authorized representative of the food establishment so investigated.

(b) Failure by any food establishment to fully comply with all corrective actions recommended by an inspector shall cause all food products stored or offered for sale therein to be deemed to be “adulterated” within the meaning of Section 21a-101 of the Connecticut

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General Statutes. The sale of such adulterated food shall subject the operator of such food establishment to the penalties enumerated in Section 21a-95 of the Connecticut General Statutes.

(c) Prior to reporting any violation to a prosecuting attorney, the commissioner or his duly authorized representative shall notify the operator in writing, advising him of the reasons for which such disciplinary action is being contemplated. The notice shall specify a time, date and place for an informal hearing before the commissioner to be held pursuant to the provisions of Section 21a-97 (b) of the Connecticut General Statutes.

(d) At the hearing the respondent shall be given an adequate opportunity to be heard and to show why disciplinary action is not warranted. The respondent may be accompanied by counsel, if he so chooses.

(e) If the respondent offers no satisfactory explanation for his failure to eliminate the alleged unsanitary conditions, the violations shall be duly reported to a prosecuting attorney for the institution of criminal proceedings.

(f) The commissioner is additionally authorized, pursuant to section 21a-94 of the Connecticut General Statutes, to apply to the Superior Court for a temporary or permanent injunction restraining the respondent from violating any provision of section 21a-93 of the Connecticut General Statutes.

(g) Any person allegedly aggrieved by the decision of the commissioner at such a hearing may appeal the decision by initiating appropriate proceedings in the Superior Court for the judicial district of Hartford.

(Effective June 22, 1990; Amended September 1, 2005; Amended October 11, 2016)

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Sec. 21a-102-1—21a-102-6. Repealed

Repealed June 22, 1990.

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Connecticut Food, Drug and Cosmetic Act

Sec. 21a-115-1. Application of regulations. Definitions

(a) The provisions of regulations promulgated under the Connecticut Food, Drug and Cosmetic Act with respect to the doing of any act shall be applicable also to the causing of such act to be done.

(b) The definitions and interpretations of terms contained in section 21a-92 of the general statutes shall be applicable also to such terms when used in regulations promulgated under the act.

(Effective July 27, 1984)

Sec. 21a-115-2. Labeling

(a) Labeling includes all written, printed or graphic matter accompanying an article at any time while such article is in intrastate commerce or held for sale after shipment or delivery in intrastate commerce.

(b) The existence of a difference of opinion, among experts qualified by scientific training and experience, as to the truth of a representation made or suggested in the labeling is a fact (among other facts) the failure to reveal which may render the labeling misleading, if there is a material weight of opinion contrary to such representation.

(Effective July 27, 1984)

Sec. 21a-115-3. Effect of signing guaranty

In case of the giving of a guaranty or undertaking referred to in section 21a-95 (c) of the general statutes, each person signing such guaranty or undertaking shall be considered to have given it.

(Effective July 27, 1984)

Sec. 21a-115-4. Limited or general and continuing guaranties. Forms

(a) A guaranty or undertaking referred to in section 21a-95 of the general statutes may be (1) limited to a specific shipment or other delivery of an article, in which case it may be a part of or attached to the invoice or bill of sale covering such shipment or delivery; or (2) general and continuing, in which case, in its application to any shipment or other delivery of an article, it shall be considered to have been given at the date such article was shipped or delivered by the person who gives the guaranty or undertaking.

(b) The following are suggested forms of guaranty or undertaking under section 21a-95 (c) of the general statutes.

(1) (Limited form for use on invoice or bill of sale.)

(Name of person giving the guaranty or undertaking) hereby guarantees that no article listed herein is adulterated or misbranded within the meaning of the Connecticut Food, Drug and Cosmetic Act, or is an article which may not under the provisions of section 21a-103

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or 21a-110 of the general statutes, as amended, be introduced into commerce.

(Signature and post-office address of person giving the guaranty or undertaking.)

(2) (General and Continuing Form.)

The article comprising each shipment or other delivery hereafter made by (name of person giving the guaranty or undertaking) to, or on the order of (name and post-office address of person to whom the guaranty or undertaking is given) is hereby guaranteed, as of the date of such shipment or delivery, to be, on such date, not adulterated or misbranded within the meaning of the Connecticut Food, Drug and Cosmetic Act, and not an article which may not, under the provisions of section 21a-103 or 21a-110 of the general statutes, as amended, be introduced into commerce.

(Signature and post-office address of person giving the guaranty or undertaking.)

(c) A guaranty or undertaking, if signed by two or more persons, shall state that such persons severally guarantee the article to which it applies.

(d) No representation or suggestion that an article is guaranteed under the act shall be made in labeling.

(Effective July 27, 1984)

Sec. 21a-115-5. Hearings

(a) Presentation of views under subsection (b) of section 21a-97 of the general statutes shall be private and informal. The views presented shall be confined to matters relevant to the contemplated proceedings. Such views may be presented in person by the person to whom the notice was given, or by his representative. In case such person holds a guaranty or undertaking referred to in section 21a-95 (c) of the general statutes applicable to the article on which such notice was based, such guaranty or undertaking, or a verified copy thereof, shall be made a part of such presentation of views.

(b) Upon request seasonably made by the person to whom a notice appointing a time and place for the presentation of views under subsection (b) of section 21a-97 of the general statutes has been given, or by his representative, such time or place, or both such time and place, may be changed if the request states reasonable grounds therefor. Such request shall be addressed to the office of the commissioner of consumer protection.

(Effective July 27, 1984)

Sec. 21a-115-6. Examination of samples

(a) For the purpose of this section the term “examination,” as applied to samples collected, includes analyses or tests or other examinations.

(b) When an officer or employee of the commissioner of consumer protection collects a sample of a food, drug or cosmetic for examination under the act, he shall collect at least twice the quantity estimated by him to be sufficient for examination, unless (1) the amount of the article available and reasonably accessible for sampling is less than twice the quantity so estimated; (2) the cost of twice the quantity so estimated exceeds five dollars; (3) the article is perishable; (4) the examination consists principally of rapid analytical procedures,

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organoleptic examination, or other field inspection examinations or tests, made at the place where the sample is collected or in a mobile or temporary laboratory.

(c) The Connecticut Agricultural Experiment Station or the state department of health is authorized to destroy (1) any sample when they determine that no examination of such sample will be made; (2) any sample or part thereof when the commissioner determines that no notice under subsection (b) of section 21a-97 of the general statutes, and no case under the act, is or will be based on such sample; (3) any sample or part thereof when the sample was the basis of a notice under said subsection (b) of section 21a-97 and when, after opportunity for presentation of views following such notice, the commissioner determines that no other such notice, and no case under the act, is or will be based on such sample; (4) any sample or part thereof when the sample was the basis of a case under the act which has gone to final judgment, and when the commissioner determines that no other such case is or will be based on such sample; (5) any sample or part thereof if the article is perishable; (6) any sample or part thereof when, after collection, such sample or part has become decomposed or otherwise unfit for examination.

(See G.S. § 21a-116.)

(Effective July 27, 1984)

Sec. 21a-115-7. Misbranded food

(a) Among representations in the labeling of a food which render such food misbranded is a false or misleading representation with respect to another food or a drug, device or cosmetic.

(b) The labeling of a food which contains two or more ingredients may be misleading by reason, among other reasons, of the designation of such food in such labeling by a name which includes or suggests the name of one or more but not all of such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling.

(See G.S. §§ 21a-100, 21a-102.)

(Effective July 27, 1984)

Sec. 21a-115-8. Food label requirements. Exemptions

(a) If a food is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase which reveals the connection such person has with such food, such as “Manufactured for and Packed by,” “Distributed by,” or other similar phrase which expresses the facts.

(b) The statement of the place of business shall include the street address, if any, of such place, unless such street address is shown in a current city directory or telephone directory.

(c) Where a person manufactures, packs or distributes a food at a place other than his principal place of business, the label may state the principal place of business in lieu of the actual place where each package of such food was manufactured or packed or is to be distributed, if such statement is not misleading in any particular.

(d) The requirement that the label shall contain the name and place of business of the

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manufacturer, packer or distributor shall not be considered to relieve any food from the requirement that its label shall not be misleading in any particular.

(e) (1) The statement of the quantity of the contents shall reveal the quantity of food in the package, exclusive of wrappers and other material packed with such food. (2) The statement shall be expressed in the terms of weight, measure or numerical count or a combination of numerical count and weight or measure, which are generally used by consumers to express quantity of such food and which give accurate information as to the quantity thereof. If no general consumer usage in expressing accurate information as to the quantity of such food exists, the statement shall be in terms of liquid measure if the food is liquid, or in terms of weight if the food is solid, semi-solid, viscous or a mixture of solid and liquid.

(f) (1) A statement of weight shall be in terms of the avoirdupois pound and ounce. A statement of liquid measure shall be in terms of the United States gallon of two hundred thirty-one cubic inches and quart, pint and fluid ounce subdivisions thereof, and, except in case of frozen food which is so consumed, shall express the volume at 68° F. (20° C.). A statement of dry measure shall be in terms of the United States bushel of 2150.42 cubic inches and peck, dry quart and dry pint subdivisions thereof or in terms of the United States standard barrel and its subdivisions of third, half and three-quarters barrel. In the case of an export shipment, the statement may be in terms of a system of weight or measure in common use in the country to which such shipment is exported. (2) A statement of weight or measure in the terms specified in subdivision (1) of this subsection may be supplemented by a statement in terms of the metric system of weight or measure. (3) Unless an unqualified statement of numerical count gives accurate information as to the quantity of food in the package, it shall be supplemented by such statement of weight, measure or size of the individual units of the foods as will give such information.

(g) Statements shall contain only such fractions as are generally used in expressing the quantity of the food. A common fraction shall be reduced to its lowest terms; a decimal fraction shall not be carried out to more than two places.

(h) (1) If the quantity of food in the package equals or exceeds the smallest unit of weight or measure which is specified in subsection (f) of this section, and which is applicable to such food under the provisions of subsection (e) (2) of this section, the statement shall express, except as provided in subdivision (2) of this subsection, the number of the largest of such units contained in the package (for example, the statement on the label of a package which contains one quart of food shall be "1 quart," and not "2 pints" or "32 fluid ounces"). Where such number is a whole number and a fraction, there may be substituted for the fraction its equivalent in smaller units, if any smaller is specified in subsection (f) (for example, 1¼ quarts may be expressed as "1 quart 1½ pints" or "1 quart 1 pint 8 fluid ounces"; 1¼ pounds may be expressed as "1 pound 4 ounces"). The stated number of any unit which is smaller than the largest unit, specified in subsection (f), contained in the package shall not equal or exceed the number of such smaller units in the next larger unit so specified (for example, instead of "1 quart 16 fluid ounces" the statement shall be "1½

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quarts” or “1 quart 1 pint”; instead of “24 ounces” the statement shall be “1½ pounds” or “1 pound 8 ounces”). (2) In the case of a food with respect to which there exists an established custom of stating the quantity of the contents as a fraction of a unit, which unit is larger than the quantity contained in the package, or as units smaller than the largest unit contained therein, the statement may be made in accordance with such custom if it is informative to consumers.

(i) (1) Statement of quantity shall express the minimum or the average. If the statement is not so qualified as to show that the quantity expressed is the minimum, it shall be considered to express the average quantity in the package. (2) The average weight, measure or numerical count of the contents of at least six packages shall fully equal the weight, measure or numerical count stated on the package. In the case of bread, section 21a-154 of the general statutes requires the average weight to be determined on the basis of twelve packages.

(j) A food shall be exempt from compliance with the requirements of subdivision (2) of subsection (e) of section 21a-102 of the general statutes, if (1) the quantity of the contents, as expressed in terms applicable to such food under the provisions of subsection (e) (2) of this section, is less than one-half ounce avoirdupois, or less than one-half fluid ounce, or, in case the units of the food can be easily counted without opening the package, less than six units; or (2) the statement of the quantity of the contents of the package, together with all other words, statements and information required by or under authority of the act to appear on the label, cannot, because of insufficient label space, be so placed on the label as to comply with the requirements of section 21a-102 of the general statutes and regulations promulgated thereunder.

(Effective July 27, 1984)

Sec. 21a-115-9. Inadequate labels; use of label space; language of labels and labeling

(a) A word, statement or other information required by or under authority of the act to appear on the label may lack that prominence and conspicuousness required by section 21a-102 (f) of the general statutes by reason, among other reasons, of (1) the failure of such word, statement or information to appear on the part or panel of the label which is presented or displayed under customary conditions of purchase; (2) the failure of such word, statement or information to appear on two or more parts or panels of the label, each of which has sufficient space therefor, and each of which is so designed as to render it likely to be, under customary conditions of purchase, the part or panel displayed; (3) the failure of the label to extend over the area of the container or package available for such extension, so as to provide sufficient label space for the prominent placing of such word, statement or information; (4) insufficiency of label space, for the prominent placing of such word, statement, or information resulting from the use of label space for any word, statement, design or device which is not required by or under authority of the act to appear on the label; (5) insufficiency of label space, for the prominent placing of such word, statement or information, resulting from the use of label space to give materially greater conspicuousness

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to any other word, statement or information, or to any design or device; or (6) smallness or style of type in which such word, statement or information appears, insufficient background contrast, obscuring designs or vignettes, or crowding with other written, printed or graphic matter.

(b) No exemption depending on insufficiency of label space, as prescribed in regulations promulgated under section 21a-102 of the general statutes shall apply if such insufficiency is caused by (1) the use of label space for any word, statement, design or device which is not required by or under authority of the act to appear on the label; (2) the use of label space to give greater conspicuousness to any word, statement or other information than is required by section 21a-102 of the general statutes; or (3) the use of label space for any representation in a foreign language.

(c) (1) All words, statements and other information required by or under authority of the act to appear on the label or labeling shall appear thereon in the English language. (2) If the label contains any representation in a foreign language, all words, statements and other information required by or under authority of the act to appear on the label shall appear thereon in the foreign language. (3) If the labeling contains any representation in a foreign language, all words, statements and other information required by or under authority of the act to appear on the label or labeling shall appear on the labeling in the foreign language.

(Effective July 27, 1984)

Sec. 21a-115-10. Nonconformity to definitions and standards

In the following conditions, among others, a food does not conform to the definition and standard of identity therefor: (a) If it contains an ingredient for which no provision is made in such definition and standard; (b) if it fails to contain any one or more ingredients required by such definition and standard; (c) if the quantity of any ingredient or component fails to conform to the limitation, if any, prescribed therefor by such definition and standard.

(See G.S. §§ 21a-100, 21a-102.)

(Effective July 27, 1984)

Sec. 21a-115-11. Designation of ingredients. Misleading labels. Exemptions and variations

(a) The name of an ingredient, except a spice, flavoring or coloring which is an ingredient of a food other than one sold as a spice, flavoring or coloring, required by section 21a-102 of the general statutes to be borne on the label of a food, shall be a specific name and not a collective name. But if an ingredient, which itself contains two or more ingredients, conforms to a definition and standard of identity prescribed by regulations under section 21a-100 of the general statutes, such ingredient may be designated on the label of such food by the name specified in the definition and standard, supplemented, in case such regulations require the naming of optional ingredients present in such ingredient, by a statement showing the optional ingredients which are present in such ingredient.

(b) No ingredient shall be designated on the label as a spice, flavoring or coloring unless

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it is a spice, flavoring or coloring, as the case may be, within the meaning of such term as commonly understood by consumers. The term “coloring” shall not include any bleaching substance.

(c) An ingredient which is both a spice and a coloring, or both a flavoring and a coloring, shall be designated as spice and coloring, or flavoring and coloring, as the case may be, unless such ingredient is designated by its specific name.

(d) A label may be misleading by reason, among other reasons, of (1) the order in which the names of ingredients appear thereon, or the relative prominence otherwise given such names; or (2) its failure to reveal the proportion of, or other fact with respect to, an ingredient, when such proportion or other fact is material in the light of the representation that such ingredient was used in fabricating the food.

(e) (1) A food shall be exempt from the requirements of subdivision (2) of section 21a-102 (i) of the general statutes, if all words, statements, and other information required by or under authority of the act to appear on the label of such food, cannot, because of insufficient label space, be so placed on the label as to comply with the requirements of section 21a-102 (f) of the general statutes and regulations promulgated thereunder. But such exemption shall be on the condition that, if the omission from the label of the statement of the quantity of the contents affords sufficient space to state legibly thereon all the information required by such subdivision (2), such statement of the quantity of the contents shall be omitted as authorized by section 21a-115-8 (j) (2) and the information required by said subdivision (2) shall be so stated as prominently as practicable even though the statement is not of such conspicuousness as to render it likely to be read by the ordinary individual under customary conditions of purchase. (2) In the case of an assortment of different items of food, when variations in the item which make up different packages packed from such assortment normally occur in good packing practice, and when such variations result in variations in the ingredients in different packages, such food shall be exempt from compliance with the requirements of subdivision (2) of subsection (i) of section 21a-102 of the general statutes with respect to any ingredient which is not common to all packages. But such exemption shall be on the condition that the label shall bear, in conjunction with the names of such ingredients as are common to all packages, a statement in terms which are as informative as practicable and which are not misleading, indicating that other ingredients may be present.

(Effective July 27, 1984)

Sec. 21a-115-12. Food containing artificial flavoring, artificial coloring or chemical preservative

(a) (1) The term “artificial flavoring” means a flavoring containing any sapid or aromatic constituent, which constituent was manufactured by a process of synthesis or other similar artifice. (2) The term “artificial coloring” means a coloring containing any dye or pigment, which dye or pigment was manufactured by a process of synthesis or other similar artifice, or a coloring which was manufactured by extracting a natural dye or natural pigment from

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a plant or other material in which such dye or pigment was naturally produced. (3) The term “chemical preservative” means any chemical which, when added to food, tends to prevent or retard deterioration thereof; but does not include common salt, sugars, vinegar, spices or oils extracted from spices, or substances added to food by direct exposure thereof to wood smoke.

(b) A food which is subject to the requirements of section 21a-102 of the general statutes shall bear the labeling, even though such food is not in package form.

(c) A statement of artificial flavoring, artificial coloring or chemical preservative shall be placed on the food, or on its container or wrapper, or on any two or all of these, as may be necessary to render such statement likely to be read by the ordinary individual under customary conditions of purchase and use of such food.

(d) A food shall be exempt from compliance with the requirements of section 21a-102 of the general statutes if it is not in package form and the units thereof are so small that a statement of artificial flavoring, artificial coloring or chemical preservative, as the case may be, cannot be placed on such units with such conspicuousness as to render it likely to be read by the ordinary individual under customary conditions of purchase and use.

(See G.S. § 21a-102 (k).)

(Effective July 27, 1984)

Sec. 21a-115-13. Standards of identity and quality for egg nog beverage

(a) For the purpose of this section the term “milk products” means milk fat and milk solids not fat, made from pure, wholesome, unadulterated pasteurized milk.

(b) The term “egg nog” means a clean, wholesome food product, made from two or more of the following ingredients: (1) Milk products; (2) eggs; (3) sucrose and/or dextrose; (4) spices; (5) wholesome edible stabilizer; (6) salt.

(c) Optional ingredients may include: (1) Harmless artificial flavor; (2) harmless artificial color.

(d) Egg nog shall contain not less than six per cent by weight of milk fats, not less than one per cent by weight of egg yolk solids, not more than one-half of one percent by weight of stabilizer and not more than fifty thousand standard plate colonies of bacteria per gram.

(See G.S. § 21a-100.)

(Effective July 27, 1984)

Sec. 21a-115-14. Definitions and standards and labeling regulations for meat and meat products

(a) **Flesh.** Flesh is an edible part of the striated muscle of an animal. The term “animal,” as herein used, indicates a mammal, a fowl, a fish, a crustacean, a mollusk or any other animal used as a source of food.

(b) **Meat.** Meat is the properly dressed flesh derived from cattle, from swine, from sheep or from goats sufficiently mature and in good health at the time of slaughter, but restricted to that part of the striated muscle which is skeletal or that which is found in the tongue, in

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the diaphragm, in the heart or in the esophagus, and does not include that found in the lips, in the snout or in the ears, with or without the accompanying and overlying fat and the portions of bone, skin, sinew, nerve and blood vessels which normally accompany the flesh and which may not have been separated from it in the process of dressing it for sale. The term “meat,” when used in a qualified form, as, for example, “horse meat,” “reindeer meat,” “crab meat,” etc., is then, and then only, properly applied to corresponding portions of animals other than cattle, swine, sheep and goats.

(c) **Fresh meat.** Fresh meat is meat which has undergone no substantial change in character since the time of slaughter.

(d) **Beef.** Beef is meat derived from cattle nearly one year of age or older.

(e) **Veal.** Veal is meat derived from young cattle one year or less in age.

(f) **Mutton.** Mutton is meat derived from sheep nearly one year of age or older.

(g) **Lamb.** Lamb is meat derived from young sheep one year or less in age.

(h) **Pork.** Pork is meat derived from swine.

(i) **Venison.** Venison is flesh derived from deer.

(j) **Hamburg, hamburger.** Hamburg or hamburger is comminuted fresh beef, with or without addition of suet. It contains not more than thirty per cent of fat.

(k) **Meat loaf.** Meat loaf is the product consisting of a mixture of comminuted meat with spice and/or with cereals, with or without milk and/or eggs, pressed into the form of a loaf and cooked.

(l) **Sausage.** The term “sausage” as used herein means the products commercially known as “sausage,” including varieties that are fresh, dried, smoked or cooked, whether or not packed in casings. The more familiar varieties of sausage are pork sausage and sausage of Frankfort, Vienna and Bologna styles. Pork sausage and breakfast sausage, whether fresh, smoked or canned, shall not contain more than fifty per cent of fat.

(m) **Optional ingredients.** (1) Cereal, vegetable starch, starchy vegetable flour, soya flour, dried milk or dried skim milk may be added to sausage, provided the presence of such added material shall be declared in the manner hereinafter described and the amount of any one of these substances, or any combination of them, shall not exceed three and one-half per cent. (2) For the purpose of facilitating grinding, chopping and mixing, not more than three per cent of water or ice may be added to sausage which is not cooked and to luncheon meat; sausage of the type which is cooked, such as Frankfort style, Vienna style and Bologna style, may contain not more than ten per cent of added water or moisture to make the product palatable. (3) Certified artificial coloring may be used in the preparation of sausage casings, but when so used the fact shall be declared in the manner hereinafter provided. (4) No preservative may be used in meat or meat products sold, or required by definition to be, fresh meat. Permissible preservative and curing agents for preserved meats and meat products are common salt, sugar (sucrose), corn sugar (dextrose), wood smoke, vinegar, spices, sodium nitrate, sodium nitrite, potassium nitrate (saltpeter), potassium nitrite, disodium phosphate and benzoate of soda. The sale of meats containing sodium sulphite or other salt of sulphurous acid is prohibited. The use of any of the nitrates or nitrites listed

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above shall not result in the presence of nitrite nitrogen equivalent to more than two hundred parts per million of sodium nitrite in the finished product. The maximum quantities of sodium nitrite and/or potassium nitrite that may be used are as follows: Two pounds in one hundred gallons of pickle; or one ounce for each one hundred pounds of meat in dry salt, dry cure or box cure; or one-quarter ounce in one hundred pounds of chopped meat and/or meat by-products. With appropriate declaration, the following preservatives may be added, in the amounts indicated, to render animal fat or a combination of such fat and vegetable fat: (A) Resin guaiac not to exceed $\frac{1}{10}$ of 1 per cent; or (B) nordihydroguaiaretic acid not to exceed $\frac{1}{100}$ of 1 per cent; or (C) tocopherols not to exceed $\frac{3}{100}$ of 1 per cent; or (D) lecithin; or (E) citric acid not to exceed $\frac{1}{100}$ of 1 per cent; or (F) citric or phosphoric acid not to exceed $\frac{5}{1000}$ of 1 per cent, in combination with not more than $\frac{1}{100}$ of 1 per cent of nordihydroguaiaretic acid; or (G) propyl gallate not to exceed $\frac{1}{100}$ of 1 per cent; or (H) propyl gallate not to exceed $\frac{1}{100}$ of 1 per cent in combination with not more than $\frac{5}{1000}$ of 1 per cent of citric acid; or (I) thiodipropionic acid, dilauryl thiodipropionate, distearyl thiodipropionate or combinations thereof in quantities not to exceed $\frac{1}{100}$ of 1 per cent of thiodipropionic acid and $\frac{9}{100}$ of 1 per cent of either dilauryl thiodipropionate or distearyl thiodipropionate or combinations of the two; or (J) butylated hydroxyanisole (a mixture of 2-tertiary-butyl-4-hydroxyanisole and 3-tertiary-butyl-4 hydroxyanisole) or combinations of butylated hydroxyanisole with nordihydroguaiaretic acid or propyl gallate with or without the addition of citric or phosphoric acid, in quantities not to exceed $\frac{2}{100}$ of 1 per cent of butylated hydroxyanisole, or $\frac{1}{100}$ of 1 per cent of nordihydroguaiaretic acid plus $\frac{2}{100}$ of 1 per cent of butylated hydroxyanisole, or $\frac{1}{100}$ of 1 per cent propyl gallate plus $\frac{2}{100}$ of 1 per cent of butylated hydroxyanisole. Citric or phosphoric acid, not to exceed $\frac{5}{1000}$ of 1 per cent, may be added with any of these.

(n) **Labeling of unpagged meat products.** (1) When the optional ingredients, or any of them, mentioned in subdivision (1) of subsection (m) are added to sausage, the product shall be marked with the name of each of such added ingredients, as, for example, “cereal added,” “potato flour added,” “cereal and potato flour added,” “soya flour added,” “dried skim milk added,” “cereal and dried skim milk added,” etc., as the case may be. (2) When a meat product is placed in casings to which artificial coloring is applied, the article shall be legibly and conspicuously marked by stamping or printing on the casing or securely affixing to the article the words “artificially colored,” provided when the casing is colored, prior to its use as a covering for the product, with coloring of such kind and so applied as not to be transferrable to the product and not to be misleading or deceptive, the casing may be marked with the words “casing colored” prominently displayed. (3) A cloth bag, artificial casing or similar container of sausage or other meat product of a size larger than that customarily sold at retail intact shall be printed with such markings as “casing colored,” “artificially colored,” “cereal added,” “dried skim milk added” and “imitation,” near each end of the article, so as to be clearly visible to the consumer. (4) The markings indicated in subdivision (3) of this subsection shall be branded near each end of sausage or similar products prepared in animal casings when the article is of a size larger than customarily sold at retail intact.

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(5) When a preservative permitted in subparagraphs (A) to (J), inclusive, of subdivision (4) of subsection (m) of this section is added to sausage or other meat food products in casings, the product shall be marked to show the presence and percentage of the added preservative.

(6) A product fabricated from two or more ingredients shall bear a list of the ingredients as required by section 21a-102 (i) (2) of the Connecticut Food, Drug and Cosmetic Act, and this list shall comply with all the requirements of section 21a-115-11. The list of ingredients shall be applied legibly and securely to the product by means such as stamping, printing or the use of paper bands, tags or tied-in paper or fabric flaps on stuffed sausage, or tissue strips on loaf-like articles. Bockwurst and sausages of the smaller varieties, such as frankfurters and pork sausage, shall bear the list of ingredients at least once on each two pounds of product. When such product is distributed in an immediate or true container of a type and size customarily sold at retail intact, the list of ingredients on the label of the package shall be sufficient.

(o) **Labeling of packaged meat products** (1) When any product is placed in any can, pot, tin, canvas or other receptacle or covering constituting an immediate or true container, there shall be affixed to such container or covering a label giving (A) the true name of the product; (B) the word “ingredients” followed by a list of the ingredients when the product is fabricated from two or more ingredients; (C) the name and place of business of the manufacturer, packer or distributor; and (D) an accurate statement of the quantity of the contents. Plain wrappings for fresh meat, such as dressed carcasses and principal parts thereof, which are used solely to protect the product against soiling or excessive drying during transportation or storage need not bear labels; and uncolored transparent coverings, such as cellophane, which bear no printed or graphic matter and which enclose any unpackaged or packaged product bearing all required markings need not bear labels if the required markings are clearly legible through such coverings. Meat or meat products designed to be cut into portions that are weighed for the consumer at the time of sale need not be labeled with statements of their net weights. (2) Folders and similar coverings made of paper or like material, which do not completely enclose the product and which bear any printed word or statement, shall bear all features required on a label for an immediate or true container. (3) No container or covering which bears or is to bear a label shall be filled, in whole or in part, except with a product which is sound, healthful, wholesome and fit for human food, and which is strictly in accordance with the statements on the label. (4) The name of a product shall be the common name, if any, and one which clearly and completely identifies the article. A product which has been prepared by salting, smoking, drying, cooking, chopping and the like shall be so described on the label unless the name on the article implies, or the manner of packaging shows, that the product was subjected to such procedure or procedures. The unqualified terms “meat,” “meat by-product,” “meat food product,” and terms common to the meat industry but not to consumers such as “picnic,” “butt,” “cala,” “square,” “loaf,” “spread,” “delight,” “roll,” “plate,” “luncheon” and “daisy” shall not be used as names of articles unless accompanied with terms descriptive of the products or with lists of ingredients. (5) The list of ingredients shall appear as pof or in

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addition to the true name of the product and shall comply with all the requirements of section 21a-102 (i) (2) of the Connecticut Food, Drug and Cosmetic Act and section 21a-115-11. For example, the name of an ingredient shall not be a collective name but a specific name, such as “beef,” “pork,” “beef tripe,” “sheep livers,” “pork snouts,” “flour,” “corn flour,” “potato flour,” “water,” “dried skim milk,” “tomato puree” and “beef broth.” When a product is coated with pork fat, gelatin or other approved substance and a specific declaration of such coating appears in connection with the name of the product, the ingredient statement need not make reference to the ingredients of such coating. (6) No statement, word, picture, design or device which conveys any false impression or gives any false indication of origin or quality shall appear on any label. For example: (A) Terms having geographical significance with reference to a locality other than that in which the product is prepared may appear on the label only when qualified by the word “style,” “type” or “brand,” as the case may be, in the same size and lettering as in the geographical term, and accompanied with a prominent qualifying statement identifying the country, state, territory or locality in which the product is prepared, using terms appropriate to effect the qualification. When the word “style” or “type” is used, there shall be a recognized style or type of product identified with and peculiar to the locality represented by the geographical term and the product shall possess the characteristics of such style or type, and the word “brand” shall not be used in such a way as to be false or deceptive. A geographical term which has come into general usage as a trade name may be used without the qualifications provided for in this subparagraph. The terms “Frankfurter,” “Vienna,” “Bologna,” “Braunschweiger,” “Milan,” “Polish,” and their modifications, as applied to sausages, the terms “Brunswick” and “Irish” as applied to stews, and the term “Boston” as applied to pork shoulder butts, need not be accompanied by the word “style,” “type” or “brand” or a statement identifying the locality in which the product is prepared. (B) Such terms as “farm,” “country” and the like shall not be used on labels in connection with products unless such products are actually prepared on the farm or in the country. If the product is prepared in the same way as on the farm or in the country these terms, if qualified by the word “style” in the same size and style of lettering, may be used. The term “farm” may be used as part of a brand designation when qualified by the word “brand” in the same size and style of lettering, and followed with a statement identifying the locality in which the product is prepared. Sausage containing cereal shall not be labeled “farm style” or “country style” and lard not rendered in an open kettle shall be designated as “farm style” or “country style.” (C) The terms “spring lamb” and “genuine spring lamb” are applicable only to carcasses of new-crop lambs slaughtered during the period beginning in March and terminating not beyond the close of the week containing the first Monday in October. (D) Coverings shall not be of such color, design or kind as to be misleading or deceptive with respect to color, quality or kind of product to which they are applied. For example, transparent or semitransparent coverings for such articles as sliced bacon or pork sausage shall not bear lines or other designs of red or other color which give a false impression of leanness of the product. (E) The word “fresh” shall not be used on labels to designate a product which contains any sodium nitrate, sodium

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nitrite, potassium nitrate, potassium nitrite or benzoate of soda or which has been salted for preservation. (F) The words “spice,” “spices” and “spiced,” without qualification, shall not be used unless they refer to genuine natural spice. (G) As used on labels of meat or any meat product, the term “gelatin” shall mean (i) the jelly prepared by cooking pork skins, tendons or connective tissue and (ii) dry commercial gelatin or the jelly resulting from its use. (H) Any product, other than a canned product, labeled with the term “loaf” as its name or part of its name shall be prepared in loaf form with sufficient stability to withstand handling before being placed in a wrapper, casing or the like. (I) The term “baked” shall apply only to a product which has been cooked by the direct action of dry heat and for a sufficient time to permit the product to assume the characteristics of a baked article, such as the formation of a brown crust on the surface, rendering out of surface fat, and the caramelization of the sugar if applied. Baked loaves shall be heated to a temperature of at least 160°F. and baked pork cuts shall be heated to an internal temperature of at least 170°F. (J) When a product such as a loaf is browned by dipping in hot edible oil or by a flame, its label shall state such fact, the words “Browned in Hot Cottonseed Oil” or “Browned by a Flame,” as the case may be, appearing as part of the name of the product. (K) The term “meat” and the names of particular kinds of meat, such as beef, veal, mutton, lamb and pork, shall not be used in such a manner as to be misleading or deceptive. (L) The word “ham,” without any prefix indicating the species of animal from which derived, shall be used on labels only in connection with pork hams. Ham shanks as such or ham shank meat as such or the trimmings accruing in the trimming and shaping of hams shall not be labeled “ham” or “ham meat” without qualification. When used in connection with a chopped product, the term “ham” or “ham meat” shall not include the skin. (M) The terms “shankless” and “hockless” shall apply only to ham and pork shoulders from which the shank or hock has been completely removed, thus eliminating the entire tibia and fibula, or radius and ulna, respectively, together with the overlying muscle, skin and other tissue. (N) Such terms as “meat extract” or “extract of beef” without qualification shall not be used on labels in connection with products prepared from organs or parts of the carcass other than fresh meat. Extracts prepared from any parts of the carcass other than fresh meat shall not be labeled “meat extract” but may be properly labeled with the true name of the parts from which prepared. In the case of extracts in fluid form, the word “fluid” shall also appear on the label, as, for example, “fluid extract of beef.” Meat extracts shall contain not more than twenty-five per cent of moisture. Fluid extract of meat shall contain not more than fifty per cent of moisture. (O) When cereal, vegetable starch, starchy vegetable flour, soya flour, dried milk or dried skim milk is added to sausage, there shall appear on the label in a prominent manner, contiguous to the name of the product, the name of each such added ingredient, as, for example, “cereal added,” “with cereal,” “potato flour added,” “cereal and potato flour added,” “soya flour added,” “dried skim milk added,” “cereal and dried skim milk added,” as the case may be. (P) When any product is enclosed in a container along with a packing substance such as brine, vinegar or agar jelly, a declaration of the packing substance shall be printed prominently on the label in connection with the name of the

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product, as, for example, “frankfurts packed in brine,” “lamb tongue packed in vinegar,” or “beef tongue packed in agar jelly,” as the case may be. The statement of the quantity of contents shall represent the weight of the drained product when removed from the container to the exclusion of the packing substance. The packing substance shall not be used in such a manner as will result in the container being so filled as to be misleading. (Q) The term “lard” is applicable only to the fat rendered from fresh, clean, sound, fatty tissues from hogs in good health at the time of slaughter, with or without lard stearin or hydrogenated lard. The tissues do not include bones, detached skin, head skins, ears, tails, organs, windpipes, large blood vessels, scrap fat, skimmings, settlings, pressings and the like, and are reasonably free from muscle tissue and blood. (R) The term “leaf lard” is applicable only to lard prepared from fresh leaf fat. (S) The term “rendered pork fat” is applicable to the fat other than lard, rendered from clean, sound carcasses, parts of carcasses, or edible organs from hogs in good health at the time of slaughter, except that stomachs, bones from the head and bones from cured or cooked pork are not included. The tissues rendered are usually fresh, but may be cured, cooked or otherwise prepared and may contain some meat food products. Rendered pork fat may be hardened by the use of lard stearin and/or hydrogenated lard and/or rendered pork fat stearin and/or hydrogenated rendered pork fat. (T) When lard or hardened lard is mixed with rendered pork fat or hardened rendered pork fat, the mixture shall be designated as “rendered pork fat” or “hardened rendered pork fat,” as the case may be. (U) Oil, stearin, or stock obtained from beef or mutton fats rendered at a temperature above 170°F. shall not be designated as “oleo oil,” “oleo stearin,” or “oleo stock,” respectively. (V) When not more than twenty per cent of beef fat, mutton fat, oleo stearin, vegetable stearin or hardened vegetable fat is mixed with lard or with rendered pork fat, there shall appear on the label, contiguous to and in the same size and style of lettering as the name of the product, the words “beef fat added,” “mutton fat added,” “oleo stearin added,” “vegetable stearin added,” or “hardened vegetable fat added,” as the case may be. (W) The designation “vegetable fat” is applicable to vegetable oil, vegetable stearin, or a combination of such oil and stearin, where the designations “vegetable oil” and “vegetable stearin” shall be applicable only to the oil and the stearin, respectively. (X) No rendered edible animal fat or mixture of fats containing rendered edible animal fat shall contain added water, except that puff-pastry shortening may contain not more than ten per cent of water, and oleomargarine may contain water within the limits prescribed by section 45.0 of the Federal Definitions and Standards for Food. (Y) Containers of edible rendered animal fats and mixtures of edible fats containing animal fats shall, before or immediately after filling, be legibly marked with the true name of the product. (Z) Products labeled “chile con carne” shall contain not less than forty per cent of meat. Head meat, cheek meat and heart meat exclusive of the heart cap may be used to the extent of twenty-five per cent of the meat ingredient under specific declaration on the label. The mixture may contain not more than eight per cent, individually or collectively, of cereal or soya flour. (AA) Products labeled “chile con carne with beans” shall contain not less than twenty-five per cent of meat. Head meat, cheek meat and heart meat exclusive of the heart cap may be used to the extent of

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twenty-five per cent of the meat ingredient under specific declaration on the label. (BB) Products labeled “hash” shall contain not less than thirty-five per cent of meat computed on the weight of the cooked and trimmed meat. The weight of the cooked meat used in this calculation shall not exceed seventy per cent of the uncooked weight of the fresh meat. Corned beef hash shall not be made with cereal, vegetable flour, dried skim milk or similar substances. Beef cheek meat and beef head meat from which the overlying glandular and connective tissues have been removed, and beef heart meat, exclusive of the heart cap, may be used individually or collectively to the extent of five per cent of the meat ingredient in the preparation of corned beef hash. (CC) Products labeled as meat stews, for example, “beef stew,” “lamb stew” and the like shall contain not less than twenty-five per cent of meat. (DD) Products labeled “tamales” shall contain not less than twenty-five per cent of meat. When tamales are packed in sauce or gravy the name of the product shall include a prominent reference to the sauce or gravy, for example, “Tamales with Sauce,” or “Tamales with Gravy.” Products labeled “Tamales with Sauce” or “Tamales with Gravy” shall contain not less than twenty per cent meat. (EE) Spaghetti with meat balls and sauce, spaghetti with meat and sauce, and similar products, shall contain not less than twelve per cent of meat. The presence of the sauce or gravy constituent shall be declared prominently on the label as part of the name of the product. Meat balls may be prepared with not more than twelve per cent, singly or collectively, of farinaceous material, soya flour, dried skim milk and the like. (FF) Spaghetti sauce with meat shall contain not less than six per cent of meat. (GG) Scrapple shall contain not less than forty per cent of meat and/or meat byproducts. The meal or flour used may be derived from grain and/or soybeans. (HH) Liver sausage, liver loaf, liver paste, liver cheese, liver pug, liver spread and the like shall contain not less than thirty per cent of liver. (II) Products labeled “ham spread,” “tongue spread” and the like shall contain not less than fifty per cent of the meat ingredient named, to the exclusion of other meat and meat byproducts except fat. (JJ) Deviled ham may contain added ham fat, provided the total fat content shall not exceed thirty-five per cent of the finished product. The moisture content of deviled ham, deviled tongue, and the like, shall not exceed that of the fresh unprocessed meat. (KK) Potted meat food products and deviled meat food products shall not contain cereal, vegetable flour, dried skim milk and similar substances. The amount of water added to potted meat food products and deviled meat food products shall be limited to that necessary to replace moisture lost during processing. (LL) Cooked, cured or pickled pigs’ feet, pigs’ knuckles, and the like, shall be labeled to show that the bones remain in the product, if such is the case. The designation “semiboneless” shall not be used if less than fifty per cent of the total weight of bones has been removed. (MM) Canned products labeled “Corned Beef” and canned products labeled “Roast Beef Parboiled and Steam Roasted” shall be prepared so that the weight of the finished product shall not exceed seventy per cent by weight of the fresh beef, plus salt and flavoring material included in the product. Beef cheek meat and beef head meat from which the overlying glandular and connective tissues have been removed, and beef heart meat, exclusive of the heart cap, may be used individually or collectively to the extent of five per cent of the meat ingredient in the

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preparation of canned products labeled “Corned Beef” or “Roast Beef Parboiled and Steam Roasted.” (NN) When monoglycerides and diglycerides are added to rendered animal fat or a combination of such fat and vegetable fat, there shall appear on the label in a prominent manner and contiguous to the name of the product a statement such as “With Monoglycerides and Diglycerides,” “Monoglycerides and Diglycerides Added,” “With Diglycerides and Monoglycerides” or “Diglycerides and Monoglycerides Added,” as the case may be. (OO) Canned products labeled “Tripe with Milk” shall be prepared so that the finished canned article will contain at least sixty-five per cent tripe exclusive of the cooked-out juices and milk. The product shall be prepared with not less than ten per cent milk. (PP) Products labeled “Beans with Frankfurters in Sauce,” “Sauerkraut with Wieners and Juice,” and the like, shall contain not less than twenty per cent of frankfurters or “wieners.” (QQ) Products labeled “Lima Beans with Ham in Sauce,” “Beans with Ham in Sauce,” “Beans with Bacon in Sauce,” and the like, shall contain not less than twelve per cent of ham or bacon. (RR) Products labeled “Chow Mein Vegetables with Meat” and “Chop Suey Vegetables with Meat” shall contain not less than twelve per cent meat.

(See G.S. § 21a-100.)

(Effective July 27, 1984)

Sec. 21a-115-15. Names of drugs; difference from standards to be indicated

(a) The name by which a drug is designated shall be clearly distinguishing and differentiating from any name recognized in an official compendium unless such drug complies in identity with the identity prescribed in an official compendium under such recognized name.

(b) The term “drug defined in an official compendium” means a drug having the identity prescribed for a drug in an official compendium.

(c) A statement that a drug defined in an official compendium differs in strength, quality or purity from the standard of strength, quality or purity set forth for such drug in an official compendium shall show all the respects in which such drug so differs, and the extent of each such difference.

(See 1963 Supp. § 21a-105.)

(Effective July 27, 1984)

Sec. 21a-115-16. Labeling of drugs and devices; false or misleading representations

(a) Among representations in the labeling of a drug or device which render such drug or device misbranded is a false or misleading representation with respect to another drug or device or a food or cosmetic.

(b) The labeling of a drug which contains two or more ingredients may be misleading by reason, among other reasons, of the designation of such drug in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling.

(See 1963 Supp. § 21a-106.)

(Effective July 27, 1984)

Sec. 21a-115-17. Labeling of drugs and devices; information re manufacturer, packer or distributor; statement of quantity

(a) If a drug or device is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase which reveals the connection such person has with such drug or device, such as “Manufactured for and Packed by,” “Distributed by,” “Retailled by,” or other similar word or phrase which expresses the facts.

(b) The statement of the place of business shall include the street address, if any, of such place, unless such street address is shown in a current city directory or telephone directory.

(c) Where a person manufactures, packs or distributes a drug or device at a place other than his principal place of business, the label may state the principal place of business in lieu of the actual place where each package of such drug or device was manufactured or packed or is to be distributed, if such statement is not misleading in any particular.

(d) The requirement that the label shall contain the name and place of business of the manufacturer, packer or distributor shall not be considered to relieve any drug or device from the requirement that its label shall not be misleading in any particular.

(e) (1) The statement of the quantity of the contents of a package of a drug shall reveal the quantity of such drug in the package, exclusive of wrappers and other material packed with such drug. (2) The statement shall be expressed in the terms of weight, measure or numerical count, or a combination of numerical count and weight or measure, which are generally used by consumers and users of such drug to express quantity thereof and which give accurate information as to such quantity. But if no general usage in expressing accurate information as to the quantity of such drug exists among consumers and users thereof, the statement of the quantity of a drug which is not in tablet, capsule, ampul or other unit form shall be in terms of weight if the drug is solid, semi-solid or viscous, or in terms of measure if the drug is liquid; the statement of the quantity of a drug which is in such unit form shall be in terms of the numerical count of such units, supplemented, when necessary to give accurate information as to the quantity of such drug in the package, by such statement, in such terms, manner and form as are not misleading, of the weight or measure of such units, or of the quantity of each active ingredient in each such unit, as will give such information. (3) The statement of the quantity of a device shall be expressed in terms of numerical count.

(f) A statement of weight shall be in terms of the avoirdupois pound, ounce and grain, or of the kilogram, gram and milligram. A statement of liquid measure shall be in terms of the United States gallon of two hundred thirty-one cubic inches and quart, pint, fluid ounce and fluid dram subdivisions thereof, or of the liter, milliliter or cubic centimeter, and shall express the volume at 68°F. (20°C.).

(g) Statements of the quantity of a drug shall contain only such fractions as are generally used in expressing the quantity of such drug. A common fraction shall be reduced to its

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lowest terms; a decimal fraction shall not be carried out to more than three places, except in the case of a statement of the quantity of an active ingredient in a unit of a drug.

(h) (1) Unless made in accordance with the provisions of subdivision (2) of this subsection, a statement of the quantity of a drug, in the terms of weight or measure applicable to such drug under the provisions of subsection (e) (2) of this section, shall express the number of the largest unit specified in subsection (f) of this section which is contained in the package (for example, the statement on the label of a package which contains one pint of a drug shall be “1 pint,” and not “16 fluid ounces”). Where such number is a whole number and a fraction, there may be substituted for the fraction its equivalent in smaller units, if any smaller is specified in said subsection (f) (for example, 1¼ pounds may be expressed as “1 pound 4 ounces”). The stated number of any unit which is smaller than the largest unit, specified in said subsection (f), contained in the package shall not equal or exceed the number of such smaller units in the next larger unit so specified (for example, instead of “1 quart 16 fluid ounces” the statement shall be “1½ quarts” or “1 quart 1 pint”). (2) In the case of a drug with respect to which there exists an established custom of stating the quantity of the contents as a fraction of a unit, which unit is larger than the quantity contained in the package, or as units smaller than the largest unit contained therein, the statement may be made in accordance with such custom if it is informative to consumers.

(i) The statement of the quantity of a drug or device shall express the minimum quantity, or the average quantity, of the contents of the package. If the statement is not so qualified as to show definitely that the quantity expressed is the minimum quantity, the statement, except in the case of ampuls, shall be considered to express the average quantity. The statement of the quantity of a drug in ampuls shall be considered to express the minimum quantity.

(j) Where the statement expresses the minimum quantity, no variation below the stated minimum shall be permitted except variations below the stated weight or measure of a drug caused by ordinary and customary exposure, after such drug is introduced into commerce, to conditions which normally occur in good distribution practice and which unavoidably result in decreased weight or measure. Variations above the stated minimum shall not be unreasonably large. In the case of a liquid drug in ampuls the variation above the stated measure shall comply with the excess volume prescribed by any official compendium for filling of ampuls.

(k) Where the statement does not express the minimum quantity (1) variations from the stated weight or measure of a drug shall be permitted when caused by ordinary and customary exposure, after such drug is introduced into commerce, to conditions which normally occur in good distribution practice and which unavoidably result in change of weight or measure; (2) variations from the stated weight, measure or numerical count of a drug or device shall be permitted when caused by unavoidable deviations in weighing, measuring or counting the contents of individual packages which occur in good packing practices. But under this subdivision (2) variations shall not be permitted to such extent that the average of the quantities in the packages comprising a shipment or other delivery of the

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drug or device is below the quantity stated and no unreasonable shortage in any package shall be permitted, even though overages in other packages in the same shipment or delivery compensate for such shortage.

(l) The extent of variations from the stated quantity of the contents permissible under subsections (j) and (k) of this section in the case of each shipment or other delivery shall be determined by the facts in such case.

(m) A drug or device shall be exempt from compliance with the requirements of subsection (b) (2) of section 21a-106 of the general statutes if (1) the statement of the quantity of the contents, as expressed in terms applicable to such drug or device under the provisions of subsection (e) (2) of this section, together with all other words, statements and information required by or under authority of the act to appear on the label of such drug or device, cannot, because of insufficient label space, be so placed on the labels as to comply with the requirements of said section 21a-106 and regulations promulgated thereunder; or (2) the quantity of the contents of the package, as expressed in terms of numerical count in compliance with subsection (e) (2) or (3) of this section is less than six units and such units can be easily counted without opening the package.

(Effective July 27, 1984)

Sec. 21a-115-18. Inadequate labeling. Language

(a) A word, statement or other information required by or under authority of the act to appear on the label may lack that prominence and conspicuousness required by section 21a-106 (c) of the general statutes by reason, among other reasons, of (1) the failure of such word, statement or information to appear on the part or panel of the label which is presented or displayed under customary conditions of purchase; (2) the failure of such word, statement or information to appear on two or more parts or panels of the label, each of which has sufficient space therefor, and each of which is designed as to render it likely to be, under customary conditions of purchase, the part or panel displayed; (3) the failure of the label to extend over the area of the container or package available for such extension, so as to provide sufficient label space for the prominent placing of such word, statement or information; (4) insufficiency of label space, for the prominent placing of such word, statement or information, resulting from the use of label space for any word, statement, design or device which is not required by or under authority of the act to appear on the label; (5) insufficiency of label space, for the prominent placing of such word, statement or information, resulting from the use of label space to give materially greater conspicuousness to any other word, statement or information, or to any design or device; or (6) smallness or style of type in which such word, statement or information appears, insufficient background contrast, obscuring designs or vignettes, or crowding with other written, printed or graphic matter.

(b) No exemption depending on insufficiency of label space, as prescribed in regulations promulgated under section 21a-106 of the general statutes, shall apply if such insufficiency is caused by (1) the use of label space for any word, statement, design or device which is

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not required by or under authority of the act to appear on the label; (2) the use of label space to give greater conspicuousness to any word, statement or other information than is required by section 21a-106 (c) of the general statutes, or (3) the use of label space for any representation in a foreign language.

(c) (1) All words, statements and other information required by or under authority of the act to appear on the label or labeling shall appear thereon in the English language. (2) If the label contains any representation in a foreign language, all words, statements and other information required by or under authority of the act to appear on the label shall appear thereon in the foreign language. (3) If the labeling contains any representation in a foreign language, all words, statements and other information required by or under authority of the act to appear on the label or labeling shall appear on the labeling in the foreign language.

(See 1963 Supp. § 21a-106.)

(Effective July 27, 1984)

Sec. 21a-115-19. Labeling of drugs; names; quantity; warning

(a) (1) The name of a substance or derivative required by or under authority of section 21a-106 of the general statutes to be borne on the label of a drug shall be the common or usual name of such substance or derivative, unless it is designated solely by a name recognized in an official compendium and such designation complies with the provisions of said section 21a-106. (2) A statement on the label of a drug of the name of a constituent, which constituent is a chemical derivative of a substance named in said section 21a-106 shall show the substance from which such constituent is derived and that such constituent is a derivative thereof.

(b) (1) If the drug is in tablet, capsul, ampul or other unit form, the statement of the quantity or proportion of such substance or derivative contained therein shall express the weight or measure of such substance or derivative in each such unit. If the drug is not in such unit form, the statement shall express the weight or measure of such substance or derivative in a specified unit of weight or measure of the drug. Such statement shall be in terms which are informative to the ordinary consumer and user of the drug. (2) The statement of the percentage of such substance or derivative contained in a drug shall express the percentage by weight; except that, if both the substance or derivative and the drug are liquid, the statement may express the percentage by volume at 68°F. (20°C.), but in such case the statement shall be so qualified as to show definitely that the percentage is expressed by volume.

(c) The names and quantities or proportions of all such substances and derivatives, and the statement “Warning—May be habit forming,” shall immediately precede or immediately follow, without intervening written, printed or graphic matter, the name by which such drug is titled in the part or panel of the label thereof which is presented or displayed under customary conditions of purchase.

(d) A drug shall not be considered to be misbranded by reason of failure of its label to bear the statement “Warning—May be habit forming” (1) if such drug is not suitable for

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internal use, and is distributed and sold exclusively for such external use as involves no possibility of habit formation; or (2) if the only substance or derivative subject to section 21a-106 (d) of the general statutes contained in such drug is chlorobutanol, which is present solely as a preservative and in a quantity not more than 0.5 per cent by weight, and such drug is for parenteral use only; or (3) if the only substance or derivative subject to said section 21a-106 (d) contained in such drug is chlorobutanol, which is present as an analgesic or as an analgesic and a preservative in a quantity not more than 3.0 per cent and such drug contains one or more active ingredients and is for parenteral use only.

(Effective July 27, 1984)

Sec. 21a-115-20. Name and quantity statement requirements; derivatives or preparations of substances

(a) (1) The name of an ingredient, substance, derivative or preparation required by said section 21a-106 of the general statutes to be borne on the label of a drug shall be the name thereof which is listed in said section, or, if not so listed, shall be a specific name and not a collective name. But if an ingredient is an article the name of which is recognized in an official compendium and such article complies with the specifications set forth therefor in such compendium, such ingredient may be designated on the label of such drug by the common or usual name under which such specifications are so set forth. (2) Where an ingredient contains a substance the quantity or proportion of which is required by said section 21a-106 to appear on the label, and such ingredient is not a derivative or preparation of such substance as defined in subsection (b) (1) of this section, the label shall bear, in conjunction with the name of the ingredient, a statement of the quantity or proportion of such substance in such drug. (3) An abbreviation or chemical formula shall not be considered to be a common or usual name. The name "acetphenetidin" shall be considered to be the same as the name "acetphenetidin," "aminopyrine" the same as "amidopyrine." The name "alcohol," without qualification, means ethyl alcohol.

(b) (1) A derivative or preparation of a substance named in section 21a-106 of the general statutes is an article which is derived or prepared from such substance by any method, including actual or theoretical chemical action. (2) A statement on the label of a drug of the name of an ingredient thereof, which ingredient is a derivative or preparation of a substance named in said section 21a-106 shall show the substance from which such ingredient is derived or prepared and that such ingredient is a derivative or preparation thereof.

(c) (1) If the drug is in tablet, capsule, ampul or other unit form, the statement of the quantity or proportion of a substance, derivative or preparation contained therein shall express the weight or measure of such substance, derivative or preparation in each such unit. If the drug is not in such unit form, the statement shall express the weight or measure of such substance, derivative or preparation in a specified unit of weight or measure of the drug, or the percentage of such substance, derivative or preparation in such drug. Such statement shall be in terms which are informative to the ordinary consumer and user of the drug. (2) A statement of the percentage of alcohol shall express the percentage of absolute

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alcohol by volume at 60°F. (15.56°C.). A statement of the percentage of a substance, derivative or preparation other than alcohol shall express the percentage by weight; except that, if both the substances, derivative or preparation and the drug containing it are liquid, the statement may express the percentage by volume at 68°F. (20°C.), but in such case the statement shall be so qualified as to show definitely that the percentage is expressed by volume.

(d) In case a statement of the quantity or proportion of a derivative or preparation in a drug is not as informative, to consumers or users of such drug, of the activity or consequences of use thereof as a statement of the quantity or proportion of the substance from which such derivative or preparation is derived or prepared, the quantity or proportion of such substance shall also be stated on the label of such drug.

(e) A label of a drug may be misleading by reason, among other reasons, of (1) the order in which the names of ingredients, substances, derivatives or preparations appear thereon, or the relative prominence otherwise given such names; or (2) its failure to reveal the proportion of, or other fact with respect to, an ingredient, substance, derivative or preparation, when such proportion or other fact is material in the light of the representation that such ingredient, substance, derivative or preparation is a constituent of such drug.

(f) (1) A drug shall be exempt from the requirements of subparagraph (A) (ii) of subdivision (1) of subsection (E) of section 21a-106 of the general statutes if all words, statements, and other information required by or under authority of the act to appear on the label of such drug, cannot, because of insufficient label space, be so placed on the label as to comply with the requirements of said section 21a-106 and regulations promulgated thereunder. But such exemption shall be on the condition that, if the omission from the label of the statement of the quantity of the contents affords sufficient space to state legibly thereon all the information required by said subparagraph (A) (ii), such statement of the quantity of the contents shall be omitted as authorized by section 21a-115-17 (m) (1), and the information required by said subparagraph (A) (ii) shall be so stated as prominently as practicable even though the statement is not of such conspicuousness as to render it likely to be read by the ordinary individual under customary conditions of purchase. (2) A drug shall be exempt from the requirements of said subparagraph (A) (ii) with respect to the alkaloids, atropine, hyoscyne or hyoscyamine contained in such drug, if such alkaloid is contained therein as a constituent of belladonna, hyoscyamus, scopolia, stramonium, or other plant material, or any preparation thereof, which was used as an ingredient of such drug, and no practical and accurate method of analysis exists for the quantitative determination of each such alkaloid in such ingredient. But such exemption shall be on the condition that the label of such drug shall state the quantity or proportion of total alkaloids contained therein as constituents of such ingredient.

(Effective July 27, 1984)

Sec. 21a-115-21. Directions for use; exemptions

(a) Directions for use may be inadequate by reason, among other reasons, of omission,

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in whole or in part, or incorrect specification of (1) directions for use in all conditions for which such drug or device is prescribed, recommended, or suggested in its labeling, or in its advertising disseminated or sponsored by or on behalf of its manufacturer or packer, or in such other conditions, if any, for which such drug or device is commonly and effectively used; (2) quantity of dose, including quantities for persons of different ages and different physical conditions; (3) frequency of administration or application; (4) duration of administration or application; (5) time of administration or application, in relation to time of meals, time of onset of symptoms or other time factor; (6) route or method of administration or application; or (7) preparation for use (shaking, dilution, adjustment of temperature or other manipulation or process).

(b) A shipment or other delivery of a drug or device shall be exempt from compliance with the requirements of section 21a-106 of the general statutes in the following cases: (1) A drug or device which because of its toxicity or because of the degree of skill required in its administration cannot be used with safety except by or under the supervision of a physician, dentist or veterinarian; provided the label of such drug or device shall bear the statement "Caution—to be used only by or on the prescription of a physician" (dentist or veterinarian as the case may be); (2) official drugs which are dispensed only after compounding with other substances in filling prescriptions of physicians, dentists or veterinarians; (3) inactive ingredients of drugs such as solvents, colorings and flavorings; (4) drugs and devices shipped to physicians, dentists or veterinarians, hospitals or clinics, for use in professional practice and under professional supervision; (5) a drug or device intended solely for use in the manufacture of other drugs and devices; provided the label of such drug or device bears the statement "for manufacturing purposes only." The term "manufacture" does not include compounding of a prescription issued by a physician, dentist or veterinarian, in his professional practice; (6) common household preparations, adequate directions for the use of which are known by the ordinary individual.

(See 1963 Supp. § 21a-106 (f).)

(Effective July 27, 1984)

Sec. 21a-115-22. New drugs

Newness of a drug may arise by reason, among other reasons, of (a) the newness for drug use of any substance which composes such drug, in whole or in part, whether it is an active substance or a menstruum, excipient, carrier, coating or other component; (b) the newness for drug use of a combination of two or more substances, none of which is a new drug; (c) the newness for drug use of the proportion of a substance in a combination, even though such combination containing such substance in other proportion is not a new drug; (d) the newness of use of such drug in diagnosing, curing, mitigating, treating or preventing a disease, or to affect a structure or function of the body, even though such drug is not a new drug when used in another disease or to affect another structure or function of the body; or (e) the newness of a dosage, or method or duration of administration or application, or other condition of use prescribed, recommended or suggested in the labeling of such drug, even

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though such drug when used in other dosage, or other method or duration of administration or application, or different condition, is not a new drug.

(See 1963 Supp. § 21a-92 (17).)

(Effective July 27, 1984)

Sec. 21a-115-23. Application for sale of new drugs

An application which is on its face incomplete in that it does not contain all the matter required by subparagraphs (A), (B), (C), (D) and (F) of subdivision (2) of subsection (a) of section 21a-110 of the general statutes shall not be accepted for filing. The date on which an application is received by the commissioner of consumer protection shall be considered to be the date on which such application is filed, and the commissioner shall notify the applicant of such date. If the applicant withdraws his application, such application shall be considered as not having been filed.

(Effective July 27, 1984)

Sec. 21a-115-24. Adulterated cosmetics; “coal-tar hair dye” defined

The term “coal-tar hair dye” includes all articles containing any coal-tar color or intermediate, which color or intermediate alters the color of the hair when such articles are applied to the hair under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual.

(See 1963 Supp. § 21a-111.)

(Effective July 27, 1984)

Sec. 21a-115-25. Misbranded cosmetics; false or misleading representations

(a) Among representations in the labeling of a cosmetic which render such cosmetic misbranded is a false or misleading representation with respect to another cosmetic or a food, drug or device.

(b) The labeling of a cosmetic which contains two or more ingredients may be misleading by reason, among other reasons, of the designation of such cosmetic in such labeling by a name which includes or suggests the names of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling.

(See G.S. § 21a-112.)

(Effective July 27, 1984)

Sec. 21a-115-26. Labeling of cosmetics; information re manufacturer, packer or distributor; statement of quantity

(a) If a cosmetic is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase which reveals the connection such person has with such cosmetic, such as, “Manufactured for and Packed by,” “Distributed by” or other similar phrase which expresses the facts.

(b) The statement of the place of business shall include the street address, if any, of such

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place, unless such street address is shown in a current city directory or telephone directory.

(c) Where a person manufactures, packs or distributes a cosmetic at a place other than his principal place of business, the label may state the principal place of business in lieu of the actual place where each package of such cosmetic was manufactured or packed or is to be distributed, if such statement is not misleading in any particular.

(d) The requirement that the label shall contain the name and place of business of the manufacturer, packer or distributor shall not be considered to relieve any cosmetic from the requirement that its label shall not be misleading in any particular.

(e) (1) The statement of the quantity of the contents shall reveal the quantity of cosmetic in the package, exclusive of wrappers and other material packed with such cosmetic. (2) The statement shall be expressed in the terms of weight, measure or numerical count, or a combination of numerical count and weight or measure, which are generally used by the consumers to express quantity of such cosmetic and which give accurate information as to the quantity thereof. But if no general consumer usage in expressing accurate information as to the quantity of such cosmetic exists, the statement shall be in terms of liquid measure if the cosmetic is liquid, or in terms of weight if the cosmetic is solid, semi-solid or viscous, or in such terms of numerical count, or numerical count and weight or measure, as will give accurate information as to the quantity of the cosmetic in the package.

(f) (1) A statement of weight shall be in terms of the avoirdupois pound and ounce. A statement of liquid measure shall be in terms of the United States gallon of two hundred thirty-one cubic inches and quart, pint and fluid ounce subdivisions thereof, and shall express the volume at 68°F. (20°C.). However, in the case of an export shipment, the statement may be in terms of a system of weight or measure in common use in the country to which shipment is exported. (2) A statement of weight or measure in the terms specified in subdivision (1) of this subsection may be supplemented by a statement in terms of the metric system of weight or measure. (3) Unless an unqualified statement of numerical count gives accurate information as to the quantity of cosmetic in the package, it shall be supplemented by such statement of weight, measure or size of the individual units of the cosmetic as will give such information.

(g) Statements shall contain only such fractions as are generally used in expressing the quantity of the cosmetic. A common fraction shall be reduced to its lowest terms; a decimal fraction shall not be carried out to more than two places.

(h) (1) If the quantity of cosmetic in the package equals or exceeds the smallest unit of weight or measure which is specified in subsection (f) of this section, and which is applicable to such cosmetic under the provisions of subsection (e) (2) of this section, the statement shall express the number of the largest of such units contained in the package (for example, the statement on the label of a package which contains one pint of cosmetic shall be "1 pint" and not "16 fluid ounces"), unless the statement is made in accordance with the provisions of subdivision (2) of this subsection. Where such number is a whole number and a fraction, there may be substituted for the fraction its equivalent in smaller units, if any smaller is specified in subsection (f) (for example, 1¾ quarts may be expressed as "1 quart

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1½ pints” or “1 quart 1 pint 8 fluid ounces”; ¼ pounds may be expressed as “1 pound 4 ounces”). The stated number of any unit which is smaller than the largest unit, specified in subsection (f), contained in the package shall not equal or exceed in number of such smaller units in the next larger unit so specified (for example, instead of “1 quart 16 fluid ounces” the statement shall be “1½ quarts” or “1 quart 1 pint”; instead of “24 ounces” the statement shall be “1½ pounds” or “1 pound 8 ounces”). (2) In the case of a cosmetic with respect to which there exists an established custom of stating the quantity of the contents as a fraction of a unit, which unit is larger than the quantity contained in the package, or as units smaller than the largest unit contained therein, the statement may be made in accordance with such custom if it is informative to consumers.

(i) The statement shall express the minimum quantity, or the average quantity, of the contents of the packages. If the statement is not so qualified as to show definitely that the quantity expressed is the minimum quantity, the statement shall be considered to express the average quantity.

(j) Where the statement expresses the minimum quantity, no variation below the stated minimum shall be permitted except variations below the stated weight or measure caused by ordinary and customary exposure, after the cosmetic is introduced into interstate commerce, to conditions which normally occur in good distribution practice and which unavoidably result in decreased weight or measure. Variations above the stated minimum shall not be unreasonably large.

(k) Where the statement does not express the minimum quantity (1) variations from the stated weight or measure shall be permitted when caused by ordinary and customary exposure, after the cosmetic is introduced into interstate commerce, to conditions which normally occur in good distribution practice and which unavoidably result in change of weight or measure; (2) variations from the stated weight, measure or numerical count shall be permitted when caused by unavoidable deviations in weighing, measuring or counting individual packages which occur in good packing practice. But under this subdivision variations shall not be permitted to such extent that the average of the quantities in the packages comprising a shipment or other delivery of the cosmetic is below the quantity stated, and no unreasonable shortage in any package shall be permitted, even though overages in other packages in the same shipment or delivery compensate for such shortage.

(l) The extent of variations from the stated quantity of the contents permissible under subsections (j) and (k) of this section in the case of each shipment or other delivery shall be determined by the facts in such case.

(m) A cosmetic shall be exempt from compliance with the requirements of subdivision (2) of subsection (b) of section 21a-112 of the general statutes if the quantity of the contents of the package, as expressed in terms applicable to such cosmetic under the provisions of subsection (e) (2) of this section, is less than one-fourth ounce avoirdupois, or less than one-eighth fluid ounce, or, in case the units of the cosmetic can be easily counted without opening the package, less than six units.

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(See G.S. § 21a-112.)

(Effective July 27, 1984)

Sec. 21a-115-27. Inadequate labeling. Language

(a) A word, statement or other information required by or under authority of the act to appear on the label may lack that prominence and conspicuousness required by section 21a-112 (c) of the general statutes by reason, among other reasons, of (1) the failure of such word, statement or information to appear on the part or panel of the label which is presented or displayed under customary conditions of purchase; (2) the failure of such word, statement or information to appear on two or more parts or panels of the label, each of which has sufficient space therefor, and each of which is so designed as to render it likely to be, under customary conditions of purchase, the part or panel displayed; (3) the failure of the label to extend over the area of the container or package available for such extension so as to provide sufficient label space for the prominent placing of such word, statement or information; (4) insufficiency of label space, for the prominent placing of such word, statement or information, resulting from the use of label space for any word, statement, design or device which is not required by or under authority of the act to appear on the label; (5) insufficiency of label space, for the prominent placing of such word, statement or information resulting from the use of label space to give materially greater conspicuousness to any other word, statement or information, or to any design or device; or (6) smallness or style of type in which such word, statement or information appears, insufficient background contrast, obscuring designs or vignettes, or crowding with other written, printed or graphic matter.

(b) (1) All words, statements and other information required by or under authority of the act to appear on the label or labeling shall appear thereon in the English language. (2) If the label contains any representation in a foreign language, all words, statements and other information required by or under authority of the act to appear on the label shall appear thereon in the foreign language. (3) If the labeling contains any representation in a foreign language, all words, statements and other information required by or under authority of the act to appear on the label or labeling shall appear on the labeling in the foreign language.

(Effective July 27, 1984)

Sec. APPENDIX.

**SPECIAL REGULATIONS MADE UNDER THE AUTHORITY OF THE FOOD,
DRUG AND COSMETIC ACT**

(1) Allowances for variations in weight, measure or numerical count. (Authority of section 21a-102 of the general statutes.)

Allowances for the articles listed are for individual packages.

Material	Size	Allowances, Oz.
Ale	Qt.	½

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Ale	Pt.	¼
Artichokes	No. 2	1
Asparagus	No. 2	½
Asparagus Tips	No. 1	½
Bacon	1 lb.	½
Baking Powder	¼ lb.	⅛
Baking Powder	½ lb.	¼
Beans, Kidney	No. 2	½
Beans, Lima	No. 2	½
Beans, Refugee	No. 2	½
Beans, String	No. 2	½
Beans, Wax	No. 2	½
Beef, Corned	No. 1	½
Beef, Corned	No. 2	1
Beef, Sliced	12 oz.	½
Beer	Qt.	½
Beer	Pt.	¼
Beets	No. 2	½
Biscuits and Crackers	Less than 2 oz.	⅛
Biscuits and Crackers	2.1—4.0 oz.	¼
Biscuits and Crackers	4.1—8.0 oz.	¼
Biscuits and Crackers	8.1—16.0 oz.	½
Brandy	Qt.	½
Brandy	Pt.	¼
	above	½
‡Bread	24 oz. loaf below	1
	above	1
Butter	1 lb.	¼
Carbonated Drinks	Qt.	½
Carbonated Drinks	Pt.	¼
Cherries	No. 2	½
Cherries	No. 3	1
Cherry Cider	Gal.	2
Cherry Cider	2 Qt.	1

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Cherry Cider	Qt.	½
Chicken, Boned	No. 1	½
Chili Sauce	—	½
Chocolate	4 oz.	⅛
Chocolate	8 oz.	⅛
Chow-Chow	—	½
Cider	Qt.	½
Clams	—	½
Cocoa	8 oz.	¼
Cocoa	4 oz.	⅛
Cocoanut, Shred.	¼ lb.	½
Cocoanut, Shred.	½ lb.	1
Coffee	1 lb.	½
Corn	No. 2	½
Corn Flakes	Standard	½
Cordials	Qt.	½
Cordials	Pt.	¼
Crab	—	½
Crackers (see Biscuits)	—	—
Cream	½ Pt.	¼
Cream	Pt.	¼
Cream	Qt.	½
Cream of Tartar	¼ lb.	⅛
Crisco	1 ½ lbs.	¼
°Dried Fruits	1 lb.	1
°Dried Fruits	½ lb.	½
Farina	2 lbs.	½
Fish Flakes	—	½
Flavoring Extracts	1 oz.	1/10
Flavoring Extracts	2 oz.	1/10
Flavoring Extracts	4 oz.	⅕
Flour	49 lbs.	12
Flour	24.5 lbs.	8

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Flour, Prepared	1 ½ lbs.	¼
Flour, Prepared	2 Lbs.	¼
Fruit Juices	Qt.	½
Fruit Juices	Pt.	¼
Gelatin	2 oz.	⅛
Gin	Qt.	½
Gin	Pt.	¼
Ham, Potted	¼ lb.	¼
Ham, Potted	½ lb.	¼
Herring in Tomato	—	1
Herring, Kippered	—	½
Honey, liquid or strained	—	½
Ice Cream Powder	—	¼
Jam (see Preserves)	—	—
Jelly	—	¼
Karo	2 lbs.	1
Ketchup	½ lb.	¼
Ketchup	1 lb.	¼
Macaroni	½ lb.	¼
Macaroni	1 lb.	½
Milk	Qt.	½
Milk	Pt.	¼
Milk Condensed	Baby	¼
Milk Condensed	Family	¼
Milk Condensed	Tall	½
Mince Meat	—	¼
Molasses	2 lbs.	1
Mushrooms	—	1 ½
Noodles	½ lb.	½
Oats, Rolled	Small	½
Oleomargarine	1 lb.	¼
†Olives	Large	½
†Olives	Small	¼
§Olive Oil	2 oz.	⅛

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§Olive Oil	4 oz.	1/8
§Olive Oil	8 oz.	1/4
§Olive Oil	32 oz.	1/4
Oyster Cocktail Sauce	1/2 lb.	1/8
Paprika	2 oz.	1/8
Peaches	No. 3	1
Peanut Butter	—	1/2
Pears	No. 2	1/2
Pears	No. 3	1
Peas	No. 2	1/2
Peas, Split	1 lb.	1/2
Peppers	No. 1	1/2
Peppers	No. 2	1
Pickles, Sweet	—	1/2
Pickles, Relish	—	1/2
Pineapple	No. 2	1
Plums	No. 2	1/2
Pork and Beans	No. 2	1/2
Porter	Qt.	1/2
Porter	Pt.	1/4
Preserves	—	1/2
Pumpkins	No. 3	1/2

‡Fixed by statute, Sec. 21a-154 of the general statutes.

°Based on net weights when packed, said products at the time of packing not to contain more moisture than permitted by the best trade practice.

†Or 2 Olives.

§Also other edible oils.

(Effective July 27, 1984)

Drug Wholesalers

Sec. 21a-115-28. Definitions

For the purpose of Sections 21a-115-28 through Sections 21a-115-32 the following terms shall have the meanings indicated:

- (1) “Commissioner” means the Commissioner of Consumer Protection;
- (2) “Controlled substance” means a drug as defined in Chapter 420b, Section 21a-240

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(9) of the general statutes;

(3) “Drug” means an article defined in Chapter 418, Section 21a-92 (8) of the general statutes;

(4) “Drug sample” means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug;

(5) “Legend drug” shall have the definition stated in Chapter 382, Section 20-184a of the general statutes;

(6) “Over the counter drug” means a drug which is not a legend drug;

(7) “Registration” means a wholesaler certificate of registration issued in accordance with Chapter 417, Section 21a-70 (b) of the general statutes; and

(8) “Wholesaler” means a person or firm defined in Chapter 417, Section 21a-70 (a) (1) of the general statutes who distributes a drug, except that for the purposes of these regulations such distribution does not include intracompany sales or the distribution of drug samples by manufacturers.

(Effective August 27, 1992)

Sec. 21a-115-29. Minimum information required for registration as a wholesaler

The following information shall be required for each application for a registration or a renewal of a registration:

(1) The name, full business address, and telephone number of the registrant;

(2) All trade or business names used by the registrant;

(3) Addresses, telephone numbers, and the names of contact persons for all facilities used by the registrant for the storage, handling, and distribution of prescription drugs;

(4) The type of ownership or operation (i.e., partnership, corporation, or sole proprietorship);

(5) The name(s) of the owner and/or operator of the registrant, including:

(A) If a person, the name of the person;

(B) If a partnership, the name of each partner, and the name of the partnership;

(C) If a corporation, the name and title of each corporate officer and director, the corporate name, and the name of the State of incorporation; and

(D) If a sole proprietorship, the full name of the sole proprietor and the name of the business entity;

(6) An indication as to whether the registrant will distribute controlled substances, legend drugs and/or over the counter drugs as well as a statement concerning the types of drugs to be distributed; and

(7) A change in any information in this section shall be submitted to the Commissioner within 30 days of such change.

(Effective August 27, 1992)

Sec. 21a-115-30. Multiple locations

A wholesaler operating facilities at more than one location need only obtain a single

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registration provided that it does not store or distribute controlled substances and there is joint ownership and control of all the facilities. The registrant shall provide the names and addresses of all facilities operating under the single registration and all locations shall be subject to inspection in accordance with Chapter 418, Section 21a-118 of the general statutes. If a wholesaler stores or distributes controlled substances, it shall register each facility separately.

(Effective August 27, 1992)

Sec. 21a-115-31. Personnel

Personnel employed by wholesalers shall have appropriate education and/or experience to assume responsibility for positions related to compliance with registration requirements.

(Effective August 27, 1992)

Sec. 21a-115-32. Minimum requirements for the storage and handling of drugs and for the establishment and maintenance of drug distribution records by wholesalers

(a) **Facilities.** All facilities at which drugs are stored, warehoused, handled, offered, marketed, or displayed shall:

(1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(2) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(3) Have a quarantine area for storage of drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;

(4) Be maintained in a clean and orderly condition; and

(5) Be free from infestation by insects, rodents, birds, or vermin of any kind.

(b) **Security.**

(1) All facilities operated by wholesalers shall be secure from unauthorized entry.

(2) Access from outside the premises shall be kept to a minimum and well controlled.

(3) The outside perimeter of the premises shall be well-lighted.

(4) Entry into areas where drugs are held shall be limited to authorized personnel.

(5) All facilities shall be equipped with an alarm system to detect entry after business hours.

(6) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(7) In the case of wholesalers who are also licensed as pharmacies in accordance with Chapter 382, Section 20-168 of the general statutes, subdivisions (2) and (4) of this subsection shall apply only to areas where legend drugs are stored.

(c) **Storage.**

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(1) All drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United State Pharmacopoeia/National Formulary (USP/NF).

(2) If no storage requirements are established for a drug, the drug may be held at “controlled” room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(3) Appropriate measures shall be undertaken to ensure that drugs are stored under conditions of proper temperature and humidity and that such storage conditions are adequately documented.

(4) The recordkeeping requirements in subsection (f) of this section shall be followed for all stored drugs.

(d) Examination of materials.

(1) Upon receipt each outside shipping container shall be visibly examined for identity and to prevent the acceptance of contaminated drugs or drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(2) Each outgoing shipment shall be carefully inspected for identity of the drug products and to ensure that there is no delivery of drugs that have been damaged in storage or held under improper conditions.

(3) The recordkeeping requirements in subsection (f) of this section shall be followed for all incoming and outgoing drugs.

(e) Returned, damaged, and outdated drugs.

(1) Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other drugs until they are destroyed or returned to their supplier.

(2) Any drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other drugs until they are either destroyed or returned to the supplier.

(3) If the conditions under which a drug has been returned cast doubt on the drug’s safety, identity, strength, quality, or purity, then the drug shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug’s safety, identity, strength, quality, or purity, the wholesaler shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

(4) The recordkeeping requirements in subsection (f) of this section shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated drugs.

(f) Recordkeeping.

(1) Wholesalers shall establish and maintain inventories and records of all transactions

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regarding the receipt and distribution or other disposition of drugs. These records shall include the source of the drugs, including the name and principal address of the seller or transferor, the address of the location from which the drugs were shipped or in the case of distribution the name and address of the purchaser; the identity and quantity of the drugs received and distributed or disposed of; and the dates of receipt and distribution or other disposition of the drugs. In the case of registered wholesalers who are also licensed as pharmacies in accordance with Chapter 382, Section 20-168 of the general statutes, no records shall be required to be maintained for the receipt or disposition of over-the-counter drugs.

(2) Inventories and records shall be made available for inspection and photocopying by authorized Federal, State or local officials for a period of 3 years following disposition of the drugs.

(3) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within 2 working days of a request by an authorized official of a Federal, State, or local agency.

(g) **Written Policies and Procedures.** Wholesalers shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesalers shall include in their written policies and procedures the following:

(1) A procedure whereby the oldest approved stock of a drug product is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate;

(2) A procedure to be followed for handling recalls and withdrawals of drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to: any action initiated at the request of the U. S. Food and Drug Administration or other Federal, State, or local law enforcement or government agency; any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design;

(3) A procedure to ensure that the wholesaler prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency;

(4) A procedure to ensure that any outdated drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated drugs. This documentation shall be maintained for 3 years after disposition of the outdated drugs; and

(5) In the case of wholesalers who are also licensed as pharmacies in accordance with

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Chapter 382, Section 20-168 of the general statutes, the requirements of this subsection shall apply to legend drugs only.

(h) **Responsible Persons.** Wholesalers shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

(Effective August 27, 1992)

Standards for Foods

Sec. 21a-115-33 to 21a-115-39. Reserved.

(Effective May 3, 2013)

Sec. 21a-115-40. General labeling requirements regulations

General labeling requirements regulations for food that is subject to the Connecticut Food, Drug and Cosmetic Act shall be identical to 21 CFR 1.20 to 1.24, inclusive.

(Effective May 3, 2013)

Sec. 21a-115-41. Enforcement Policy

Enforcement policy for food that is subject to the Connecticut Food, Drug and Cosmetic Act shall be identical to 21 CFR 7, Subpart A and Subpart C.

(Effective May 3, 2013)

Sec. 21a-115-42. Color additives

Packaging and labeling requirements for color additives for food shall be identical to 21 CFR 70.20 and 70.25.

(Effective May 3, 2013)

Sec. 21a-115-43. Listing of color additives for foods that are exempt from certification

Listing of colors that are exempt from certification for food shall be identical to 21 CFR 73.1 to 73.615, inclusive.

(Effective May 3, 2013)

Sec. 21a-115-44. Listing of color additives subject to certification

Listing of color additives subject to certification for food shall be identical to 21 CFR 74.101 to 74.706, inclusive.

(Effective May 3, 2013)

Sec. 21a-115-45. General specifications and general restrictions for provisional color additives for use in foods

General specifications and general restrictions for provisional color additives for use in

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foods shall be identical to 21 CFR 81.1 to 81.32, inclusive.

(Effective May 3, 2013)

Sec. 21a-115-46. Listing of certified provisionally listed colors and specifications

Listing of certified provisionally listed colors and specifications shall be identical to 21 CFR 82.3 to 82.706, inclusive.

(Effective May 3, 2013)

Sec. 21a-115-47. Table salt and iodized table salt package labeling

Package labeling for salt and iodized salt, designated as the name of salt for human food use or table salt shall be identical to 21 CFR 100.155.

(Effective May 3, 2013)

Sec. 21a-115-48. Food labeling

Food labeling shall be identical to 21 CFR 101, Subpart A to Subpart G, inclusive, except for 21 CFR 101.69 and 21 CFR 101.108.

(Effective May 3, 2013)

Sec. 21a-115-49. Common or usual name for nonstandardized foods, labeling

Common or usual names for nonstandardized foods, those foods for which a standard of identity has not been established pursuant to section 21a-100 of the Connecticut General Statutes, shall be identical to 21 CFR 102, Subpart A to Subpart B, inclusive, except for 21 CFR 102.19.

(Effective May 3, 2013)

Sec. 21a-115-50. Nutritional quality guidelines for foods

Nutritional quality guidelines for foods shall be identical to 21 CFR 104.

(Effective May 3, 2013)

Sec. 21a-115-51. Foods for special dietary use

Foods for special dietary use shall be identical to 21 CFR 105.

(Effective May 3, 2013)

Sec. 21a-115-52. Infant formula quality control procedures

Infant formula quality control procedures shall be identical to 21 CFR 106, Subpart A to Subpart C, inclusive.

(Effective May 3, 2013)

Sec. 21a-115-53. Infant formula

Infant formula shall be identical to 21 CFR 107, Subpart A to Subpart D, inclusive.

(Effective May 3, 2013)

Sec. 21a-115-54. Emergency permit control

Emergency permit control shall be identical to 21 CFR 108, Subpart B.

(Effective May 3, 2013)

Sec. 21a-115-55. Unavoidable contaminants in food for human consumption and food-packaging material

Unavoidable contaminants in food for human consumption and food-packaging material shall be identical to 21 CFR 109.

(Effective May 3, 2013)

Sec. 21a-115-56. Current good manufacturing practice in manufacturing, packing, or holding human food

Current good manufacturing practice in manufacturing, packing, or holding human food shall be identical to 21 CFR 110 or 21CFR 117, as amended from time to time.

(Effective May 3, 2013; Amended September 2, 2016)

Sec. 21a-115-57. Current good manufacturing practice for dietary supplements

Current good manufacturing practice for dietary supplements shall be identical to 21 CFR 111.

(Effective May 3, 2013)

Sec. 21a-115-58. Thermally processed low-acid foods packaged in hermetically sealed containers

Thermally processed low-acid foods packaged in hermetically sealed containers shall be identical to 21 CFR 113.

(Effective May 3, 2013)

Sec. 21a-115-59. Acidified foods

Acidified foods shall be identical to 21 CFR 114.

(Effective May 3, 2013)

Sec. 21a-115-60. Refrigeration of shell eggs held for retail distribution

Refrigeration requirements of shell eggs held for retail distribution shall be identical to 21 CFR 115.

(Effective May 3, 2013)

Sec. 21a-115-61. Hazard Analysis and Critical Control Point (HACCP) systems

Hazard Analysis and Critical Control Point (HACCP) systems shall be identical to 21 CFR 120.

(Effective May 3, 2013)

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Sec. 21a-115-62. Fish and fishery products

Fish and fishery products shall be identical to 21 CFR 123.

(Effective May 3, 2013)

Sec. 21a-115-63. Food additives

Food additives allowed in food shall be identical to 21 CFR 170, except for Sections 21 CFR 170.6, 170.15, and 170.17.

(Effective May 3, 2013)

Sec. 21a-115-64. Food additives permitted for direct addition to food for human consumption

Food additives permitted for direct addition to food for human consumption shall be identical to 21 CFR 172.

(Effective May 3, 2013)

Sec. 21a-115-65. Secondary direct food additives permitted in food for human consumption

Secondary direct food additives permitted in food for human consumption shall be identical to 21 CFR 173.

(Effective May 3, 2013)

Sec. 21a-115-66. Indirect food additives, general requirements

Indirect food additives shall be identical to 21 CFR 174.

(Effective May 3, 2013)

Sec. 21a-115-67. Indirect food additives, specific requirements for adhesives and components of coatings

Indirect food additives adhesives and components of coatings shall be identical to 21 CFR 175.

(Effective May 3, 2013)

Sec. 21a-115-68. Indirect food additives specific requirements for paper and paperboard components

Indirect food additives: paper and paperboard components shall be identical to 21 CFR 176.

(Effective May 3, 2013)

Sec. 21a-115-69. Indirect food additives specific requirements for polymers

Indirect food additives specific requirements for polymers shall be identical to 21 CFR 177.

(Effective May 3, 2013)

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Sec. 21a-115-70. Indirect food additives specific requirements for adjuvants, production aids, and sanitizers

Indirect food additives specific requirements for adjuvants, production aids, and sanitizers shall be identical to 21 CFR 178.

(Effective May 3, 2013)

Sec. 21a-115-71. Food additives permitted in food or in contact with food on an interim basis pending additional study

Food additives permitted in food or in contact with food on an interim basis pending additional study shall be identical to 21 CFR 180.

(Effective May 3, 2013)

Sec. 21a-115-72. Prior-sanctioned food ingredients

Prior-sanctioned food ingredients shall be identical to 21 CFR 181.

(Effective May 3, 2013)

Sec. 21a-115-73. Substances generally recognized as safe

Substances generally recognized as safe shall be identical to 21 CFR 182.

(Effective May 3, 2013)

Sec. 21a-115-74. Direct food substances affirmed as generally recognized as safe

Direct food substances affirmed as generally recognized as safe shall be identical to 21 CFR 184.

(Effective May 3, 2013)

Sec. 21a-115-75. Indirect food substances affirmed as generally recognized as safe

Indirect food substances affirmed as generally recognized as safe shall be identical to 21 CFR 186.

(Effective May 3, 2013)

Sec. 21a-115-76. Substances prohibited from use in human food

Substances prohibited from use in human food shall be identical to 21 CFR 189.

(Effective May 3, 2013)

Sec. 21a-115-77. Dietary supplements

Dietary supplements shall be identical to 21 CFR 190.

(Effective May 3, 2013)

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Agency

Department of Consumer Protection

Subject

Dietary Beverages

Inclusive Sections

§§ 21a-143-1—21a-143-3

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Sec. 21a-143-3.	Labeling

Dietary Beverages

Sec. 21a-143-1. Permit required to manufacture

No person, firm or corporation shall manufacture any dietary beverages or beverages containing a nonnutritive sweetening agent until a permit for said purpose has been issued by the commissioner of consumer protection. Applications shall be made on forms provided by said commissioner. Upon satisfactory proof that the applicant holds a Connecticut non-alcoholic beverage license and will fully comply with all the hereinafter mentioned requirements, the commissioner may issue such permit authorizing the manufacture and sale of dietary beverages. Such permit shall expire annually on June thirtieth.

(Effective July 27, 1984)

Sec. 21a-143-2. Sweetening agents

Dietary beverages shall be sweetened with saccharin, sodium cyclamate or other artificial sweetening agents approved by the commissioner of consumer protection.

(Effective July 27, 1984)

Sec. 21a-143-3. Labeling

Dietary beverages containing a nonnutritive sweetening agent shall bear a label upon which the following information shall be conspicuously declared: (a) The common or usual name of the product; (b) the net volume of contents; (c) the name and plant address of the bottler or packer or, in lieu of such name and address, the name and home address of the bottler or packer or the name and address of the distributor, together with the Connecticut license number of the plant bottling or packing such beverages; (d) the percentage by weight of proteins, fat and available carbohydrates; (e) the number of available calories supplied by a specified serving; (f) a declaration of artificial flavor, color or chemical preservative, and the percentage by weight of such preservative when used; (g) a complete ingredient declaration, listing all such ingredients by their common or usual names in descending order of prominence; (h) the percentage by weight and the common or usual name of the nonnutritive sweetening agent, immediately followed by an informative statement declaring the sweetening agent to be a nonnutritive artificial sweetener which should be used only by persons who must restrict their intake of ordinary sweets; (i) dietary beverages which do not contain one or more of the components referred to in subsections (d) and (e) of this section shall clearly state this fact on the label.

(Effective July 27, 1984)

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Agency

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Subject

The Manufacture of Apple Cider and Apple Juice

Inclusive Sections

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- Sec. 21a-147-10. Cleaning of containers

The Manufacture of Apple Cider and Apple Juice

Part I

Cider

Sec. 21a-147-1. Equipment

Equipment shall be housed. Equipment shall stand on a floor which can be cleaned. Dirt floors shall not be allowed in custom and commercial mills. Walls, floors and ceiling of the building shall be kept cleaned. All equipment shall be thoroughly cleaned at the end of each day's run, such cleaning to include washing and drying of cloths and scraping of racks.

(Effective July 27, 1984)

Sec. 21a-147-2. Cleaning of bottles

When second-hand bottles are used or returned bottles accepted, such bottles shall be thoroughly washed with soap and hot water and rinsed with potable water before being refilled.

(Effective July 27, 1984)

Sec. 21a-147-3. Spigots and syphons

Bottles shall be filled from a spigot or syphon started by bulb pressure. Use of mouth-started syphons is prohibited. Syphons shall be cleaned daily. Containers and spigots shall be thoroughly cleaned before refilling.

(Effective July 27, 1984)

Sec. 21a-147-4. Storage of pomace

Pomace shall be stored at least fifty feet from the building in which the cider mill is located and in such a manner as not to contribute to insanitary conditions.

(Effective July 27, 1984)

Sec. 21a-147-5. Control of communicable disease

No person suffering from any communicable or contagious disease shall be employed in or about an establishment where apple cider is manufactured or bottled. No person shall be employed in such establishment during the time in which a case of contagious disease exists in the house in which he resides, nor until such house has been disinfected, provided such person may be so employed if the local board of health issues a certificate that no danger of public contagion or infection would result from the employment of such person in such establishment.

(Effective July 27, 1984)

Sec. 21a-147-6. Labeling of containers

Each container in which cider is sold shall carry a label bearing the name of the contents,

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the name and address of the manufacturer or bottler, the volume of contents and the presence of preservative, if any is used. If any water is added to the juice, the presence and amount of such water shall be declared on the label.

(Effective July 27, 1984)

Part II

Apple Juice

Sec. 21a-147-7. Additional requirements

Manufacturers of apple juice shall abide by all regulations designated for the manufacture of apple cider and in addition shall use clean, sound apples only and shall provide concrete floors in pressing and bottling rooms, said floors to be so graded as to be easily cleaned.

(Effective July 27, 1984)

Sec. 21a-147-8. Sanitation of plant and equipment

A sufficient supply of hot and cold running water shall be available in the plant for the cleaning of equipment. Walls and ceilings shall be varnished or painted in a light color and kept clean. Doors, windows and other openings of any room in which apple juice shall be prepared and/or placed in containers shall be screened, all entrances and exits shall be equipped with automatic closing devices and each room in such establishment shall have at least one device for the catching of flies. Wash basins, sinks and toilets shall be provided for employees and no toilet shall open into any room used for the preparation or bottling of apple juice. An adequate supply of soap and single service towels shall be available for use of the employees.

(Effective July 27, 1984)

Sec. 21a-147-9. Protection from contamination

Precaution shall be taken to safeguard apple juice from contamination by dust and windborne filth.

(Effective July 27, 1984)

Sec. 21a-147-10. Cleaning of containers

New containers only shall be used unless bottle washing equipment of the type used in carbonated beverage plants is used, making it possible to soak the bottles in a solution containing three and one-half per cent alkali, of which sixty per cent shall be caustic (sodium hydroxide), for a period of at least five minutes at 120°F. and then rinsed in potable water. New containers shall be rinsed with hot water.

(Effective July 27, 1984)

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Subject

Bakeshops and Bakery Products

Inclusive Sections

§§ 21a-156-1—21a-156-7

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Sec. 21a-156-1.	Exemptions
Sec. 21a-156-2.	Labeling
Sec. 21a-156-3.	Homemade products
Sec. 21a-156-4.	Custard or cream defined
Sec. 21a-156-5.	Heating and refrigeration of custard
Sec. 21a-156-6.	Refrigeration of custard-filled products during warm weather
Sec. 21a-156-7.	Cleaning of equipment

Bakeshops and Bakery Products

Sec. 21a-156-1. Exemptions

The following products sold through interstate commerce shipments are hereby exempted from the provisions of section 21a-152 of the 1963 supplement to the general statutes: Pretzels, cookies, crackers, macaroons, bread and cracker crumbs, spaghetti, macaroni, melba toast, zwieback, Swedish crispbread, hermetically sealed containers of brown bread, plum pudding and other similar products, frozen dough and frozen mixes, bread sticks, cereal, meal and prepared mixes or other similar products, for which the commissioner deems exemptions justified.

(Effective July 27, 1984)

Sec. 21a-156-2. Labeling

All bakery products, in package form or prepacked in advance of retail sale, shall bear an ingredient declaration in the same manner as is provided for under the provisions of the Uniform Food, Drug and Cosmetic Act.

(Effective July 27, 1984)

Sec. 21a-156-3. Homemade products

The use of the terms “homemade” or “home maid,” or other similar terms, is limited to those products actually manufactured in the home and under conditions which normally prevail in the home.

Sec. 21a-156-4. Custard or cream defined

For the purpose of sections 21a-156-5 to 21a-156-7, inclusive, a cream or custard mix or cream or custard filler is defined as a material consisting principally of sugar, eggs and milk, either with or without a thickening agent, heated, cooled and applied to pastry without subsequent heating to a temperature of 180°F. or higher.

(Effective July 27, 1984)

Sec. 21a-156-5. Heating and refrigeration of custard

The custard mix shall be heated to a temperature of 180°F. or higher, then cooled immediately to a temperature of 50°F. or lower, and maintained at this temperature until used for filling.

(Effective July 27, 1984)

Sec. 21a-156-6. Refrigeration of custard-filled products during warm weather

During the months of April, May, June, July, August and September, custard-filled products shall not be manufactured or offered for sale unless they are kept under continuous refrigeration at a temperature of 50°F. or less from the time of manufacture until dispensed to the consumer. This regulation applies to hotels, restaurants and distributors, as well as to

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bakeries.

(Effective July 27, 1984)

Sec. 21a-156-7. Cleaning of equipment

All equipment and utensils with which custard filling comes in contact shall be cleaned and sterilized by a method approved by the commissioner of consumer protection.

(Effective July 27, 1984)

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Subject

The Solicitation of Charitable Funds

Inclusive Sections

§§ 21a-190k-1—21a-190k-8

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Sec. 21a-190k-2.	Charitable organization annual report
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Sec. 21a-190k-7.	Solicitation notice
Sec. 21a-190k-8.	Solicitation campaign report

The Solicitation of Charitable Funds

Sec. 21a-190k-1. Charitable organization registration statement

(a) Every charitable organization required to register with the department pursuant to section 21a-190b of the Connecticut General Statutes shall provide the following information on a registration statement furnished by the department:

- (1) The organization's full legal name and mailing address;
- (2) the organization's telephone number;
- (3) the organization's federal employer identification number;
- (4) the month the organization's fiscal year ends;
- (5) the month and year when the organization began operations;
- (6) any name or names, other than that given in subdivision (1) of subsection (a) of this section, under which funds will be solicited;
- (7) the name and address of any outside fund-raising counsel or paid solicitor which the organization plans to compensate to raise funds on its behalf in Connecticut;
- (8) the organization's tax exempt status with the United States Internal Revenue Service and whether exempt status has ever been denied or revoked;
- (9) whether the organization is incorporated, and if incorporated, the state of incorporation;
- (10) the purposes of the organization with a description of its major program activities; and
- (11) the names, residence addresses and titles of all officers, directors, trustees and key employees.

(b) The registration statement shall be signed under penalty of false statement by two authorized officers of the charitable organization.

(c) A charitable organization shall be considered as registered upon the receipt by the department of a fully completed original registration statement and the fee prescribed by section 21a-190b of the Connecticut General Statutes.

(Adopted effective June 6, 2001)

Sec. 21a-190k-2. Charitable organization annual report

The annual report required by section 21a-190c of the Connecticut General Statutes shall consist of:

(1) A form furnished by the department, which shall be signed under penalty of false statement by two authorized officers of the organization, one of whom shall be its chief fiscal officer, on which the charitable organization shall state:

- (A) Its name, address and telephone number;
- (B) the fiscal year covered by the report;
- (C) its Connecticut charities registration number as assigned to the organization upon its registration with the department;
- (D) whether during the fiscal year covered by the annual report the organization received gross revenue, exclusive of government grants and fees, in excess of the audit threshold

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established by section 21a-190c(b) of the Connecticut General Statutes;

(E) any name, other than that provided in subparagraph (A) of this section, under which funds will be solicited;

(F) whether the organization used the services of an outside fund-raising counsel or paid solicitor and the name and address of any fund-raising counsel or paid solicitor so used since the filing of the organization's last annual report;

(G) whether the organization plans to use the services of an outside fund-raising counsel or paid solicitor in the next year and the name and address of the fund-raising counsel or paid solicitor;

(H) any change in the organization's tax status with the United States Internal Revenue Service since the filing of its last annual report;

(I) any significant change in the organization's purpose since the filing of its last annual report; and

(J) whether the organization's right to solicit funds has been revoked, denied, suspended or enjoined by any state agency or by any court, or whether any such proceedings are pending and, if any of the foregoing occurred, a detailed statement of the circumstances;

(2) A completed United States Internal Revenue Service Form 990, Form 990-EZ, or Form 990-PF, whichever is appropriate for the organization, with all applicable attachments, prepared according to United States Internal Revenue Service instructions except as follows:

(A) All organizations are required to complete all parts, lines, columns and schedules of the United States Internal Revenue Service forms; and

(B) labor organizations may not file a United States Department of Labor Form LM-2 or LM-3 as a substitute for any part of Form 990 or Form 990EZ;

(3) An audit report, if one is required by section 21a-190c(b) of the Connecticut General Statutes; and

(4) The fee or fees prescribed by section 21a-190c of the Connecticut General Statutes.

(Adopted effective June 6, 2001)

Sec. 21a-190k-3. Charitable organizations exempt from registration

(a) Every charitable organization claiming an exemption from registration pursuant to section 21a-190d of the Connecticut General Statutes, shall substantiate the basis for the exemption by filing a form furnished by the department which states:

(1) Whether the organization has ever been registered under the provisions of Chapter 419d of the Connecticut General Statutes and, if the organization has been registered, its registration number;

(2) the organization's full legal name and mailing address;

(3) the organization's telephone and facsimile numbers;

(4) any name or names under which funds will be solicited other than the name given in subdivision (2) of subsection (a) of this section;

(5) whether the organization is incorporated and, if so, the state of incorporation; and

(6) the statutory basis for the exemption, and if the basis is section 21a-190d(6) of the

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Connecticut General Statutes (amount of contributions is less than the statutory threshold), a statement of its charitable purpose and major program activities.

(b) The form shall be signed under penalty of false statement by two authorized officers of the organization.

(c) For purposes of section 21a-190d(6) of the Connecticut General Statutes, “normally” means any two out of the charitable organization’s most recently completed three fiscal years.

(Adopted effective June 6, 2001)

Sec. 21a-190k-4. Fund-raising counsel registration statement

(a) Every fund-raising counsel that is required to register or renew its registration with the department pursuant to section 21a-190e(b) of the Connecticut General Statutes, shall provide the following information on a registration statement furnished by the department:

(1) Whether the fund-raising counsel has ever been registered under the provisions of Chapter 419d of the Connecticut General Statutes and, if the organization has been registered, its registration number;

(2) the fund-raising counsel’s full legal name and mailing address;

(3) the fund-raising counsel’s telephone and facsimile numbers;

(4) the names, residence addresses and titles of all officers, directors, and key employees of the fund-raising counsel;

(5) whether the fund-raising counsel is a corporation, partnership, limited liability company, individual or other entity;

(6) the year of the fund-raising counsel’s organization and the state under the laws of which the fund-raising counsel was organized; and

(7) whether the fund-raising counsel’s registration has ever been revoked, denied, suspended or enjoined by any state agency or by any court, or whether any such proceedings are pending and, if any of the foregoing has occurred, a detailed explanation of the circumstances.

(b) The registration statement shall be signed under penalty of false statement by an authorized officer of the fund-raising counsel.

(c) A fund-raising counsel shall be considered as registered upon the receipt by the department of a fully completed original registration statement and the fee prescribed by section 21a-190e(b) of the Connecticut General Statutes.

(Adopted effective June 6, 2001)

Sec. 21a-190k-5. Paid solicitor registration statement

(a) Every paid solicitor that is required to register or renew its registration with the department, pursuant to section 21a-190f(a) of the Connecticut General Statutes, shall provide the following information on a registration statement furnished by the department:

(1) Whether the paid solicitor has ever been registered under the provisions of Chapter 419d of the Connecticut General Statutes and, if the paid solicitor has been registered, its

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registration number;

(2) the paid solicitor's full legal name and mailing address;

(3) the paid solicitor's telephone and facsimile numbers;

(4) the names, residence addresses and titles of all officers and directors and all persons or entities with a twenty-five per cent or more ownership interest in the paid solicitor;

(5) whether any of the persons listed in response to subdivision (4) of subsection (a) of this section have ever been convicted by a court of any state or of the United States of any felony, or of any misdemeanor involving dishonesty or arising from the conduct of a solicitation for a charitable organization or purpose and, if any of the foregoing has occurred, a detailed explanation of the circumstances;

(6) whether the paid solicitor is a corporation, partnership, limited liability company, individual or other entity;

(7) the year of the paid solicitor's organization and the state under the laws of which the paid solicitor was organized;

(8) whether the paid solicitor is registered in other states to solicit funds and, if the paid solicitor is registered in other states, a list of those states; and

(9) whether the paid solicitor's registration has ever been revoked, denied, suspended or enjoined by any state agency or by any court, or whether any proceedings are pending and, if any of the foregoing has occurred, a detailed explanation of the circumstances.

(b) The registration statement shall be signed under penalty of false statement by an authorized officer of the paid solicitor.

(c) A paid solicitor shall be considered as registered upon the receipt by the department of a fully completed original registration statement and the fee prescribed by section 21a-190f(a) of the Connecticut General Statutes.

(Adopted effective June 6, 2001)

Sec. 21a-190k-6. Fund-raising counsel or paid solicitor bond

Fund-raising counsel required to file a bond with the department pursuant to section 21a-190e(b) of the Connecticut General Statutes and every paid solicitor shall use the following bond form:

FUND RAISING COUNSEL OR PAID SOLICITOR BOND

PLEASE READ INSTRUCTIONS BEFORE COMPLETING THIS FORM

BOND NUMBER: _____

State the name and address of the insurance agency through which this bond was purchased:

Agency Name _____

Address _____

City, State & Zip Code _____

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KNOW ALL MEN BY THESE PRESENTS:

That _____ of

Name of Fund Raising Counsel or Paid Solicitor

Address of Fund Raising Counsel or Paid Solicitor

as Principal, and _____

Name of Surety Company

a corporation organized and existing under the laws of the State of _____

Name of State

and duly authorized by law to become surety on bonds in the State of Connecticut, as Surety, are held and firmly bound jointly and severally, unto the State of Connecticut and to any person who may have a cause of action against the Principal for any liabilities arising out of the conduct of business by the Principal as Fund Raising Counsel or Paid Solicitor, in the sum of TWENTY THOUSAND DOLLARS (\$20,000.00), lawful money of the United States of America, to be paid to the Commissioner of Consumer Protection, State of Connecticut, for the use of the State of Connecticut, and to any person who may have a cause of action against the Principal for any such liabilities, as their interests may appear, not exceeding in the aggregate the said sum of TWENTY THOUSAND DOLLARS (\$20,000.00) for which payment well and truly to be made we, the Principal and Surety, bind ourselves, our heirs, executors, administrators, successors and assigns, by these presents.

WHEREAS, the above bounden Principal intends to register with the Department of Consumer Protection of the State of Connecticut as Fund Raising Counsel or Paid Solicitor for the purpose of acting as Fund Raising Counsel or Paid Solicitor for a charitable organization required to register with the Department of Consumer Protection of the State of Connecticut pursuant to the Connecticut General Statutes.

NOW, the condition of the obligation is such that if the above bounden Principal shall register as such Fund Raising Counsel or Paid Solicitor with the Department of Consumer Protection of the State of Connecticut, and said Principal shall faithfully and honestly act as such Fund Raising Counsel or Paid Solicitor in accordance with law, and fully complies with all applicable provisions of the Connecticut General Statutes, and if the Principal shall fully indemnify and save harmless from loss the State of Connecticut and any person who may have a cause of action against the Principal for any liabilities arising out of the conduct of business as such Fund Raising Counsel or Paid Solicitor, then this obligation shall be void, otherwise to be and remain in full force and effect.

This bond shall not become void upon the first recovery thereon but may be sued upon from time to time until the full amount thereof shall have been exhausted. This bond is to cover all claims arising on account of the registration of the Principal as Fund Raising Counsel or Paid Solicitor, and his acting as such.

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This bond shall be effective for the full annual term herof beginning

_____, and expiring on _____ .

Effective Date

Expiration Date

Signed this _____ day of _____, _____,

Principal (Fund Raising Counsel of Paid Solicitor)

By:

Signature and title of authorized representative of Principal

Surety

By:

Attorney-in-Fact (Attach copy of Power of Attorney)

ACKNOWLEDGMENT OF INDIVIDUAL

STATE OF _____ COUNTY OF _____

On this _____ day of _____, _____, before me personally appeared _____, known to me to be the individual whose name is subscribed in the foregoing instrument and acknowledged to me that such person executed the same for the purposes therein contained.

Notary (seal)

ACKNOWLEDGMENT OF PARTNERSHIP OR LIMITED LIABILITY COMPANY

STATE OF _____ COUNTY OF _____

On this _____ day of _____, _____, before me personally appeared _____, known to me to be the individual whose name is subscribed in the foregoing instrument and acknowledged to me that such person executed the same on behalf of said firm and for the purposes therein contained.

Notary (seal)

ACKNOWLEDGMENT OF CORPORATION

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STATE OF _____ COUNTY OF _____

On this _____ day of _____, _____, before me personally appeared _____, who acknowledged to me that such person is the _____ of _____, a corporation, and that as such corporate officer, being authorized so to do, executed the foregoing instrument for the purposes therein contained, by signing on behalf of said corporation.

Notary

(seal)

(Adopted effective June 6, 2001)

Sec. 21a-190k-7. Solicitation notice

(a) The solicitation notice required by section 21a-190f(c) of the Connecticut General Statutes shall be filed on a form furnished by the department and shall contain the following information:

- (1) The name, address and registration number of the paid solicitor;
 - (2) the name, address and registration number of the charitable organization;
 - (3) the dates on which the soliciting will begin and end;
 - (4) the minimum percentage of gross receipts guaranteed to the charitable organization by the contract required by section 21a-190f(d) of the Connecticut General Statutes;
 - (5) the method of solicitation that the paid solicitor will employ (e.g. telephone, mail, electronic media, print media, door-to-door, or other);
 - (6) if the solicitation will be conducted by telephone the notice shall disclose:
 - (A) The address and telephone number for each location from which calls will be made and the name of the office manager or person in charge at each location; and
 - (B) the names and residence addresses of all individuals who will solicit during the campaign;
 - (7) whether any person named in subdivision (6) of subsection (a) of this section has ever been convicted by any court of any state or of the United States of any felony, or of any misdemeanor involving dishonesty or arising from the conduct of a solicitation for a charitable organization or charitable purpose and, if any of the foregoing has occurred, a detailed explanation of the circumstances;
 - (8) whether the solicitation will include the sale of goods or services and, if goods or services will be sold, a description of the goods or services, and if tickets to an event will be sold, the type of event, the date of the event and the location of the event; and
 - (9) the account number, bank name and address for each bank account where receipts for the solicitation campaign will be deposited.
- (b) If soliciting is to be made orally, such as by telephone, the text of the oral presentation to be used shall be attached to the solicitation notice.

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(c) A copy of the written pledge confirmation required by section 21a-190f(f) of the Connecticut General Statutes (e.g. a receipt or invoice) shall be attached to the solicitation notice.

(d) A copy of the contract described in section 21a-190f(d) of the Connecticut General Statutes shall be filed with the solicitation notice if the contract is not already on file with the department.

(e) The truth of the solicitation notice shall be acknowledged under oath by an officer of the paid solicitor. A representative of the charitable organization shall certify to the truth of the solicitation notice under penalty of false statement.

(Adopted effective June 6, 2001)

Sec. 21a-190k-8. Solicitation campaign report

(a) The solicitation campaign financial report required by section 21a-190f(j) of the Connecticut General Statutes shall be filed on a form furnished by the department and shall contain the following information:

- (1) The name, address and registration number of the paid solicitor;
- (2) the name, address and registration number of the charitable organization;
- (3) the time period covered by the report;
- (4) the gross revenue received as of the date of the report;
- (5) the amount of uncollected pledges as of the date of the report;
- (6) an itemization of the costs of the solicitation campaign by type of expense, such as fees, salaries, or commissions to the paid solicitor, telephone, postage, printing and other expenses;
- (7) the total expenses of the campaign; and
- (8) the amount of the gross revenue retained by the charitable organization after the payment of all expenses of the campaign.

(b) The truth of the solicitation campaign report shall be acknowledged under oath by an authorized representative of the paid solicitor and by two authorized representatives of the charitable organization.

(Adopted effective June 6, 2001)

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Subject

Boxing and Sparring

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Boxing and Sparring

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(Transferred effective July 27, 2007)

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Health Clubs

Sec. 21a-224-1. Buyer's right to cancel a health club contract within three business days after receipt of said health club contract

(a) Every buyer of a health club contract may cancel said contract within three business days after the date of receipt of a copy of said contract by the buyer by mailing by certified or registered mail a written notice to the seller stating that the buyer does not wish to be bound by the health club contract.

(b) For the purpose of the definition of "business day" set forth in Connecticut General Statutes, Section 21a-216 (2), legal holidays shall be those days designated as such by Connecticut General Statutes, Section 1-4, as it may from time to time be amended.

(c) The three business day cancellation period for health club contracts shall not include the day on which the buyer received a copy of said contract.

(d) Cancellations pursuant to this section shall be without liability on the part of the buyer except for the fair market value of services actually received and the buyer shall be entitled to a refund of the entire consideration paid for the contract, if any, less the fair market value of the services or use of facilities already actually received.

(Effective July 27, 1984)

Sec. 21a-224-2. Cancellation of a health club contract when the buyer relocates further than twenty-five miles from the health club

(a) The health club contract of every buyer who relocates further than twenty-five miles from the health club facility operated by the seller or a substantially similar health club facility which would accept the seller's obligation under the contract may be cancelled at the election of the buyer.

(b) The phrase "twenty-five miles from the health club facility" shall be considered twenty-five travel miles by road, street or highway.

(c) The buyer who cancels his contract pursuant to subsection (a) of this section shall be relieved of any further obligation for payment under the contract not then due and owing at the time of the notice of cancellation. For the purpose of this subsection, the obligation under the contract then due and owing is the pro-rata portion of the contract price representing the period of time for which services were actually received.

(Effective July 27, 1984)

Sec. 21a-224-3. Cancellation of a health club contract when the buyer dies

(a) The health club contract of every buyer who dies shall be cancelled.

(b) The estate of the buyer whose contract was cancelled pursuant to subsection (a) of this section shall be relieved of any further obligation for payment under the contract not then due and owing. For the purpose of this subsection, the obligation under the contract then due and owing is the pro-rata portion of the contract price representing the period of

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time for which services were actually received.

(Effective July 27, 1984)

Sec. 21a-224-4. Buyer's right to cancel a health club contract when the buyer becomes disabled

(a) When a buyer of a health club contract becomes disabled during the membership term, the buyer shall have the option of (1) being relieved of liability for payment on that portion of the contract term for which he is disabled or (2) extending the duration of the original contract at no cost to the buyer for a period equal to the duration of the disability.

(b) "Disabled" or "disability" means a condition which has existed more than forty-five days which prevents a buyer from utilizing the health club to the same extent he utilized it before commencement of such condition.

(c) (1) If the buyer notified the health club that he has become disabled, the health club shall notify the buyer in writing within fifteen days of receipt by the health club of the buyer's notice of disability and any doctor's certificate which may be required by Connecticut General Statutes, Section 21a-217 that: (a) the health club will not require the buyer to submit to another physical examination; or (b) the health club requires the buyer to submit to another physical examination and that the buyer's obligations under the contract are suspended pending determination of disability. If the health club fails to send such written notice to the buyer within fifteen days, the health club shall be deemed to have accepted the disability.

(2) If the health club requires the buyer to submit to another physical examination, all obligations of the buyer for payment under the contract will be suspended as of the date the health club receives notice of disability. The buyers obligations will not resume until such time as a determination is made, either by consent of the buyer and the health club or through adjudicative proceedings, that disability does not exist.

(d) A buyer who is disabled may, at the buyer's option, extend the duration of the original contract at no cost to the buyer for a period equal to the duration of the disability, or remain liable for partial payment on the contract as follows:

(1) A buyer who is disabled for a period of less than the full remaining term of the contract shall only be liable for a pro-rata portion of the contract price equal to the total number of weeks specified in the contract less the number of weeks of disability, the difference being divided by the total number of weeks specified in the contract and the result of that division being multiplied by the total contract price.

(2) A buyer who is disabled for the full remaining term of the contract shall only be liable for a pro-rata portion of the contract price equal to the number of complete weeks before the commencement of disability for which the services or facilities were made available to the buyer divided by the total number of weeks specified in the contract with the result being multiplied by the total contract price.

(3) If the reasonable probabilities are that the buyer will be disabled for the full remaining term of the contract, and the buyer has elected not to extend the duration of the contract as

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provided in this subsection, the health club shall cancel the buyer's contract at the time such a determination is made and notify the buyer in writing that the contract has been cancelled.

(4) Any money paid by the buyer which is in excess of the amount for which he is liable under the provisions of this section shall be refunded by the seller to the buyer.

(5) A health club which received notice of disability from a buyer shall provide such buyer with a written form which shall fully explain the buyer's option as set forth in this subsection. Such form shall provide on it a location where the buyer shall indicate in writing the option he has chosen. Such form shall be signed by the buyer and the health club.

(Effective July 27, 1984)

Sec. 21a-224-5. Refunds

Any refund to the buyer as a result of cancellation of the contract shall be delivered by the health club to the buyer within fifteen business days of receipt by the health club of the notice of cancellation.

(Effective July 27, 1984)

Sec. 21a-224-6. Printing of other contract prices

Each health club contract shall contain a listing of the lengths of all other health club contracts and their respective prices which are currently offered for sale.

(Effective July 27, 1984)

Sec. 21a-224-7. Posting of health club contract prices and buyer's rights of cancellation

(a) Each health club shall post in a conspicuous manner the prices of all health club contracts offered for sale in every place or places where health club contracts are entered into.

(b) Each health club shall post in a conspicuous manner the three day cancellation provisions, the death and other disability provisions and the twenty-five mile moving provision of all contracts in every place or places where health club contracts are entered into.

(Effective July 27, 1984)

Sec. 21a-224-8. Repealed

Repealed August 3, 2009.

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Bedding and Upholstered Furniture

Sec. 21a-235-1. Application of regulations

The following regulations issued under authority of section 21a-235 pertain to the administration and enforcement of sections 21a-231 to 21a-235, inclusive, of the general statutes. These regulations and the provisions herein set forth apply to the manufacture, repair and renovation of all articles of bedding and upholstered furniture intended for sale and to such articles when offered for sale or resale, or exchange or lease, or consignment or delivery in consignment for sale, resale, exchange or lease, and shall apply to all persons including manufacturing establishments, both wholesale and retail, when such articles are in their possession for such purpose.

(Effective July 27, 1984)

Sec. 21a-235-2. Definitions

When used in these regulations, “commissioner” means the commissioner of consumer protection or his authorized representative; “department” means the consumer protection department; “article of bedding and upholstered furniture and filling material” means and includes such articles and parts thereof as fall within the scope of section 21a-231 of the general statutes; “sale,” “sell” or “sold” means offering or exposing for sale or resale, or exchange or lease, or consigning or delivering in consignment for sale, resale, exchange or lease, or holding in possession with like intent. The possession of any article of bedding or upholstered furniture or filling material by any maker or dealer or his agent or servant or other person in the course of business shall be presumptive evidence of intent to sell; “manufacture” means the making by hand or machine of an article of bedding or upholstered furniture or part thereof, including the assembling or processing or finishing of articles or parts produced by another and also including the processing or preparation of filling materials intended for use in the manufacture, renovation or repair of articles of bedding or upholstered furniture; “sterilize,” “sterilized” or “sterilization” means the cleaning or decontamination of any article of bedding or upholstered furniture or filling material by a process approved by the commissioner, by a person holding an active sterilization permit issued by the commissioner; “person” means an individual, partnership, corporation, firm or association, receiver, agent or other representative of such person; “license” means the formal permission granted by the commissioner to sell or manufacture for sale or remake, renovate or repair articles of bedding or upholstered furniture or filling materials within the state of Connecticut for a period not to exceed twelve calendar months beginning on October first of each year and such permission is conditioned upon the receipt and approval of an application for a license and the receipt of the required license fee; “licensee” means the person in whose name a license is recorded by the department; “valid license” or “active license” means a license which has not expired or been suspended or revoked, or voluntarily returned to the department during an annual license period; “expiration date” means September thirtieth of each year. No license is valid after said date, but licenses may be renewed in advance of the expiration date so as to become effective on October first,

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assuring a continuous active license; “registry number” means the number assigned by the commissioner to the person to whom a license is issued; “new” means any material or article which has not been previously used for any purpose and includes by-products mproduced in the processing of cotton or in the manufacture of new fabrics and materials reclaimed from new fabric and from new material, and also includes any article of bedding or upholstered furniture or filling material returned by the purchaser for exchange, alteration or correction within thirty days of the date of delivery of such article or material, provided the tags have not been removed and further provided substantial proof is at hand to determine the original date of delivery. If the article or material has been returned by the purchaser for exchange, such article or material may be sold as new provided it had not been used for any purpose. If the article or material has been used in any way it is considered as second-hand and shall comply with the provisions for second-hand merchandise. To be considered as having been returned by the purchaser for alteration or correction, the article or material shall be returned with the original tags intact and, when such alterations or corrections of error of manufacture are completed, the article may be returned to the original purchaser without sterilization but no such article may be sold as a new article; “second-hand” means any article or part thereof and any material which has been used in any manner whatsoever, including any article of bedding, upholstered furniture or filling material returned by a purchaser for exchange, alteration or correction after thirty days from the date of delivery of such articles to such person, and any article from which the tag has been removed or for which the date of original delivery to the purchaser cannot be substantiated; “antique furniture” means any article of bedding or upholstered furniture manufactured at least one hundred years prior to the date on which it is offered for sale or exchange as an antique, and such articles shall be exempt from these regulations provided substantial proof of the age of such articles shall be available to the commissioner or an authorized representative of the commissioner; “tag or identifying tag” means the tag of linen, muslin or equally durable material required to be affixed to all articles of bedding, upholstered furniture, filling material or part thereof; “labels,” “labeling” or “labeled” means the information printed on tags.

(See G.S. § 21a-231.)

(Effective July 27, 1984)

Sec. 21a-235-3. Inspection stamps

Inspection stamps are required on tags affixed to articles of bedding, upholstered furniture or filling material in the hands of retail furniture dealers or in transit to such dealers, on or before September 30, 1955, where such articles are offered for sale on October 1, 1955, or thereafter. Such articles may then be legally offered for sale by such dealers if in all other respects they conform to the provisions of statutes and regulations issued under the authority thereof, provided evidence can be furnished to substantiate the date of delivery or shipment and such evidence can be verified by the commissioner or his authorized representative.

(Effective July 27, 1984)

Sec. 21a-235-4. License requirements

(a) **Annual license.** No person shall sell or offer for sale or manufacture for sale, in the state of Connecticut, any article of bedding or upholstered furniture or filling material unless such person is licensed with the department and has been assigned a registry number and such license is valid at the time such article is sold or offered for sale in Connecticut. A license shall be valid, unless suspended or revoked in the interim, for a period of twelve months beginning on October first of one year and ending on September thirtieth of the following year. In the instance of a new licensee or licensees who are changing to a different classification or type of license, a license may be issued and registry number assigned during any quarterly period beginning on January first, April first or July first, and such license shall be valid, unless suspended or revoked, until the thirtieth day of September next following date of issue, and in such cases the fee for the license shall be prorated from the first day of the quarter in which it is issued to September thirtieth next following. All licenses expire on September thirtieth next following the date of issue, and the assigned registry number shall be withdrawn unless the license has been renewed prior to the expiration date. Except as otherwise provided in these regulations, all articles offered for sale by the licensee or in behalf of the licensee subsequent to the expiration date of a license shall be ordered “off sale” and the vendor shall be considered in violation. A license shall be valid only for the period specified on the license certificate and in no case shall a license become effective prior to the date upon which the application is approved by the department. Annual license fees shall be payable in advance with the application for the full year’s period. In the cases of prorated licenses, the fee shall be payable in advance from the beginning of the quarter in which the license is effective to September thirtieth next following the date of issue. License fees cannot be prorated if the licensee has been issued a license for any part of the previous license year. No rebate of license fees shall be made in the event a license is revoked, suspended or voluntarily returned subsequent to its issue, and only in instances of error on the part of the department shall a licensee be entitled to refund of a license fee. The annual fees for licenses shall be as follows: Manufacturer, fifty dollars; supply dealer, fifty dollars; renovator, twenty-five dollars; and second-hand dealer, twenty-five dollars.

(b) **Transferability.** Each license and the registry number assigned thereto by the commissioner is valid for use only by the person to whom it is issued and is not transferable. The misuse of any license or any registration number or the use of such license or registry number by anyone other than the person to whom it was issued shall be considered a violation and, after a hearing, the license may be cancelled and the registry number revoked. It shall be the responsibility of each person to take adequate precautions against the misuse of any license or registry number issued in his behalf.

(c) **Application for license.** Each person who intends to sell or manufacture for sale in Connecticut any article of bedding, upholstered furniture or filling material shall apply to the commissioner for a license on application forms to be provided by the commissioner. The applicant may request that the registry number issued by a cooperating state be issued to him as a Connecticut registry number, for use as a uniform registry number, but the

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granting of such request shall be at the discretion of the commissioner. Each application for a license shall be complete and shall be signed and the accuracy of the statements in the application attested by the person to whom the license is to be issued, or the principal executive when the license is to be issued in the name of a firm, partnership, corporation, organization or association. The application, when forwarded to the department, shall be accompanied by cash, check or money order, payable to the Connecticut labor department, for the established fee for one full license year, or for the prorated fee, if applicable. Inaccurate or misleading statements on any application shall be sufficient cause to refuse a license, or, if such license has been issued, shall be sufficient cause to suspend such license and withdraw the registry number. If it is determined after a hearing that the misstatements were deliberate, the license and registry number may be revoked for the balance of the license period. The commissioner may refuse to license and issue a registry number to any person when, in his opinion and after a hearing, such license and the issue of a registry number could result in danger to the life, health, comfort or economic well-being of the people with whom such person may have contact.

(d) **Registry number.** Upon approval of any application for a license the commissioner shall assign a Connecticut registry number and such number shall appear on all tags required under the provisions of sections 21a-231 to 21a-236, inclusive, of the general statutes and regulations issued under authority thereof. The commissioner may issue, as a Connecticut registry number, the number which has been assigned to the person by any other state having similar standards for the inspection, manufacture and sale of bedding and upholstered furniture and filling material where such number is to be used as a uniform registry number, if such state grants to Connecticut manufacturers the same privilege reciprocally. A Connecticut registry number is not transferable and its use by any unauthorized person shall be deemed a violation of statute, and such person shall be liable for prosecution. Licensees who intend to continue operations in Connecticut shall apply for a license in advance of the expiration date of each annual license if they desire the same Connecticut registry number.

(e) **Manufacturer's license.** Each person who manufactures for sale in Connecticut or for consignment or delivery in consignment any article of bedding or upholstered furniture or filling material shall first secure a license with the department as a manufacturer and shall have issued to him a manufacturer's license certificate and registry number. The person so licensed may manufacture for sale, at wholesale or retail, articles of bedding and upholstered furniture or filling materials subject to the laws and regulations relating to such manufacture and to such sale during the period for which the license is valid, and shall affix to such articles a tag upon which shall appear the registry number assigned by the commissioner and such other information as may be required. A licensed manufacturer may also sell, at wholesale or retail, articles manufactured by others than himself, including filling material, and may remake or renovate such articles provided each such article shall be properly tagged and such tags shall bear a valid registry number and otherwise conform with the laws and regulations governing the sale of bedding and upholstered furniture and filling materials in Connecticut.

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(f) **Supply dealer.** Each person who sells, or offers for sale in Connecticut, or consigns or delivers in consignment for such purpose, filling material, whether processed or unprocessed, or who prepares or processes filling material in bulk intended for sale in the manufacture of articles of bedding and upholstered furniture, shall first apply for a license as a supply dealer and shall have issued to him a supply dealer's license certificate and registry number, provided such person is not actively licensed as a manufacturer. The person issued a supply dealer's license may, while such license is valid, sell, offer for sale or consign for the purpose of sale filling materials for the use in the manufacture of articles of bedding and upholstered furniture subject to the provisions of statutes relating to the sale of bedding and upholstered furniture and filling materials and regulations issued under the authority thereof, and shall affix thereto a tag bearing the registry number assigned to such license. The provisions of this regulation apply to jobbers and agents, unless the principal for whom they act is properly licensed and the material sold or offered for sale is properly tagged and otherwise conforms to all of the provisions of appropriate statutes and regulations.

(g) **Renovator.** Each person who remakes, renovates or repairs any article of bedding or upholstered furniture or a part thereof, unless he holds an active manufacturer's license, shall first apply for a license with the department and have issued to him a renovator's license certificate and a registry number. The person so licensed may then remake, renovate or repair articles of bedding and upholstered furniture for customers requiring such work to be done, provided he shall affix thereto a yellow tag bearing the assigned registry number and such other information as may be required by law or regulation. Licensed renovators may offer for sale secondhand articles of bedding, upholstered furniture or filling materials, provided they shall affix thereto a yellow tag bearing the assigned registry number and other such information as is required by law or regulation relating to the sale of second-hand articles. The registry number assigned to a renovator may not be used on any but yellow tags nor shall such licensed renovator manufacture or offer for sale any article as new unless such article bears an approved tag upon which shall appear the registry number of a properly licensed manufacturer or supply dealer.

(h) **Second-hand dealer.** Each person who sells or offers for sale any secondhand article of bedding, upholstered furniture or filling material or part thereof shall first apply for a license with the department and have issued to him a second-hand dealer's license certificate and registry number unless such person is actively licensed as a manufacturer or renovator. A person so licensed shall affix to second-hand articles of bedding and upholstered furniture, a yellow tag on which shall appear the words "second-hand" and on which shall also appear the registry number assigned to the licensee and such other information as may be required and may offer such articles for sale, provided each shall conform to the laws and regulations relating to the sale of second-hand articles of bedding and upholstered furniture in Connecticut. A second-hand dealer's license shall not authorize the manufacture, renovation or repair of any article of bedding and upholstered furniture nor shall such licensee offer for sale as new any such article unless the articles shall be tagged with a proper tag bearing the registry number of the manufacturer or supply dealer. The registry number assigned to

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a second-hand dealer shall not be used on any except a yellow tag upon which shall also appear the words “second-hand.” This section shall not apply to articles sold at public auction, to the sale of antique furniture as herein defined or to the private sale from the home of the owner direct to the purchaser.

(i) **Suspension or revocation of license.** When, in the opinion of the commissioner, any licensee is in violation of any provision of sections 21a-231 to 21a-236, inclusive, of the general statutes, or any regulations issued under the authority thereof, he may summon the licensee to a hearing at which such licensee shall show cause why his license shall not be revoked for the balance of the license period. The failure of a licensee to appear at a hearing, after receiving notice of such hearing, shall be considered sufficient cause for revocation of his license and the licensee shall be immediately notified of this action. In any case where a license is suspended or revoked, all articles of bedding or upholstered furniture or filling materials bearing the registry number of such licensee shall be ordered “off sale” pending determination by the commissioner as to which, if any, of such articles may be legally sold and permission given to offer such articles for sale.

(j) **Exceptions.** The foregoing rules regarding licensing shall not apply to retail dealers in articles of bedding and upholstered furniture or to persons acting as agents in the sale of such articles, provided every article sold or offered for sale by such dealer or such agent shall be otherwise in full compliance with the statutes relating to the sale of bedding and upholstered furniture and the regulations issued under the authority thereof. Any dealer or agent offering for sale any articles not properly tagged by a licensed manufacturer, supply dealer, renovator or second-hand dealer shall be deemed in violation of the provisions of statute and subject to prosecution as provided in section 21a-236 of the general statutes, except that articles in the hands of dealers or in transit to them before the date on which the license of the manufacturer or supply dealer becomes invalid for any reason may be legally offered for sale after that date, provided evidence can be furnished and verified to substantiate the date of delivery or shipment.

(See G.S. § 21a-234.)

(Effective July 27, 1984)

Sec. 21a-235-5. Tags

Each article of bedding, upholstered furniture or filling material which is sold or offered for sale or exchange, or is in the possession of any manufacturing or mercantile establishment or other person for such purpose, shall have affixed thereto an approved identifying tag upon which shall be imprinted the registration number of the licensed manufacturer, supply dealer, renovator or second-hand dealer, and such other information as may be required by statute or these regulations. Each manufacturer, supply dealer, renovator or second-hand dealer shall supply his own tags and shall affix an approved tag to each article of bedding, upholstered furniture or package of filling material, sold or offered for sale by him or in his behalf, in such a manner that the information thereon is completely visible and so that the tag cannot be removed without destroying such tag or rendering it

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unfit for further use. Articles of bedding, upholstered furniture or packages of filling material composed of separable parts shall be tagged as required on each part. Identifying tags shall be of linen, muslin or other durable cloth material which will not flake when abraded and shall be not less than six square inches in area. Paper face tags shall not be allowed, nor shall such be approved for use. Tags shall be printed or stamped on one side only in fast black letters. Tags shall be so located that the information contained thereon is completely visible to the purchaser at all times and shall be securely sewed to the cushions, pillows, mattresses and similar articles where sewing is possible. Otherwise the tags shall be attached to the article by tacking or pasting in such manner that it cannot be removed without destruction of the tag or so that it is not fit for further use. Each piece of upholstered furniture and every piece of bedding shall have a separate tag affixed thereto in the manner described, and any article which is composed of separable parts shall have a separate tag affixed to each such part, and each tag shall contain a statement of the filling materials used in the piece to which it is attached. Only such information as is required by these regulations and by statute shall appear on any tag affixed to any article of bedding, upholstered furniture or filling materials. No advertisement, trade mark, price tag or any matter other than the required statement shall appear on or be affixed to any tag, nor shall any trade names or superfluous or substitute terms be used on such tag. The appearance of any matter other than that required or authorized in these regulations on any tag shall be sufficient cause to order "off sale" the article to which such tag is affixed. Each applicant for a license shall, on the original application or at any subsequent time that a change in tags is necessary, submit, in duplicate, a sample tag or tags, which shall be approved by the commissioner before use. Bulk filling material shall be tagged by the manufacturer or supply dealer who manufactures or processes such material and shall bear the registry number issued to such manufacturer or supply dealer, and such tags shall be affixed to each bale, bag, carton or other package of filling material when sold, exchanged, offered for sale or exchange, or delivered for use in Connecticut, except that cotton rolls, cotton bat and other filling material which are sold at retail to be used and consumed in the home of the purchaser for his personal use shall require tags as herein specified; however, any such materials that are sold for use in any article of bedding or upholstered furniture intended for sale, exchange or offer for sale shall be tagged as herein provided. Any person, including manufacturers, supply dealers or retailers, who sells or offers for sale any untagged article of bedding or upholstered furniture or package of filling materials except as herein provided without an approved and attached tag or who has such article in his possession for such purpose shall be deemed in violation of the provisions of statute and of these regulations.

(See G.S. § 21a-233.)

(Effective July 27, 1984)

Sec. 21a-235-6. Description of tags

Articles of upholstered furniture which have been remade by removing old upholstery and adding new shall be tagged in the following manner:

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(a) All cushions or detachable parts which are made entirely of new material shall bear white tags, stating that such articles consist of all new materials.

(b) A second-hand frame-work to which is attached new upholstery materials shall bear a yellow tag stating that such article consists of a second-hand frame of wood, iron or steel and filling materials, either new or second-hand.

(c) If any second-hand filling material or cover is used in any article or part of an article, a yellow tag shall be attached stating that such article or part of an article is second-hand.

(Effective July 27, 1984)

Sec. 21a-235-7. Labeling

On each identifying tag affixed to an article of bedding, upholstered furniture or package of filling material the following information shall be printed or stamped, in the English language, on one side only, in fast black ink with letters not less than one-eighth inch in height:

(a) The Connecticut registry number assigned to the licensed manufacturer, supply dealer, renovator or second-hand dealer and the name of such licensee or the name of the vendor.

(b) The name and character of the filling material contained therein which shall be described only in approved terms as hereinafter provided.

(c) When an article of bedding, upholstered furniture or package of filling materials contains two or more different kinds or types of filling material, the name and character and the percentage of each shall appear on the tag or the entire material shall be designated by the approved name of the lowest grade of material therein contained provided: (1) If an article of bedding, upholstered furniture or package of filling material contains two or more different kinds or types of filling material and the percentage of each is so stated on the tag, a tolerance of not more than ten per cent of the percentage of each kind or type of filling material named shall be allowed, and (2) no tolerance shall be allowed when filling material is described as “all,” “pure,” “100%” or terms of similar import.

(d) On each identifying tag the word “new” or “second-hand” shall also appear, in addition to the approved terms for each filling material, except as otherwise herein provided.

(e) On each identifying tag affixed to any article of bedding or upholstered furniture or package of filling material containing materials which in whole or in part have been subjected to prior use in any form, or containing material of animal or fowl origin, or containing material that is soiled, contaminated, unsanitary or that for any other reason requires sterilization in accordance with law or regulation, there shall also be imprinted thereon the words “contents sterilized” and the Connecticut permit number of the sterilizer.

(f) On each identifying tag affixed to any article of bedding or upholstered furniture or part thereof that has been remade, repaired or renovated and is to be returned to the owner, shall be imprinted, in addition to all other requirements, a statement that the article contains the same material received from the owner and a description of the kind, type and amount of filling material added, if any, and a statement that such is new or second-hand. A

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statement that the article shall not be sold but shall be returned to the owner, and the words “contents sterilized” and the Connecticut permit number of the sterilizer shall also appear.

(g) Each identifying tag affixed to any article of bedding, upholstered furniture or package of filling materials, except as otherwise provided by law or regulation, shall, in addition to all other requirements, have imprinted thereon a statement certifying that the filling materials contained in such article are described according to law and such tag, when attached to articles of bedding, upholstered furniture or package of filling material that contain all new material, shall be imprinted with the statement “date of delivery” and a space left following this statement for the insertion of the delivery date by the vendor or retail dealer.

(h) The identifying tag attached to new articles of bedding and upholstered furniture or bales, packages or cartons of filling materials shall, in addition to all other requirements, be white in color. No previously used materials may be contained in articles or packages to which a white tag is attached.

(i) The identifying tag attached to articles of bedding, upholstered furniture or bales, packages or cartons of filling material that contain any previously used material shall, in addition to all other requirements, be yellow in color.

(j) The identifying tag attached to articles of bedding or upholstered furniture that has been remade or renovated shall, in addition to all other requirements, be yellow in color.

(Effective July 27, 1984)

Sec. 21a-235-8. Use of terms and definitions relating to filling materials

Terms used to describe filling materials shall include only those set forth and defined in these regulations. Filling materials for which there is no term or definition herein may not be used until the term and definition have been approved by the department, and such term shall thereafter be used to describe such material on any tag affixed to an article, bale or package containing such material.

(a) **General terms.**

(1) The word “colored” shall precede any terms used to designate a filling material, if such material has been artificially dyed or colored.

(2) In the terms used to describe feathers and/or down, the color of the material shall precede the term. If mixed colors are used, “colored” shall precede the descriptive term.

(3) The term “shredded clippings” means any material that has been made into fabric and subsequently cut up, torn up, broken up or ground up but which has not been run through a garnett machine. The name of the material need not be included in this term but, if included, shall be as stated.

(4) The term “garnetted clippings” means any material that has been shredded and further processed by passing through a garnett machine. The name of the material need not be included in this term but, if included, shall be as stated.

(5) The word “oily” shall precede any term used to designate a filling material, if such material contains more than five per cent oil.

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(6) The term “felt” or “batting” means fiber that has been carded in layers or sheets by a garnett or felting machine. The terms “felt” or “batting” by themselves shall not be used but shall be combined with the name of the material from which they are made. If the felt has been repicked, or consists of small pieces of scrap felt, or is not readily distinguishable from unfelted material, the term “felt” or “batting” shall not be included in the descriptive term.

(7) The word “napper” means the lint removed during the process of raising the face of a cloth and shall be preceded by the name of the textile fiber or fibers from which it is made.

(8) The presence of “down fiber” or “feather fiber” in excess of ten per cent shall be set forth on the tag, together with the kind, color and percentage.

(9) The terms “rubberized” or “resin treated” shall be combined with the required descriptive term only when each hair or fiber of the specified filling material has been thoroughly coated with the stated material, rubber or resin. The terms “rubber coated” or “resin coated” shall be combined with the required descriptive term when the surface only of a filling material has been thoroughly coated with the stated material, rubber or resin. If a filling material pad is coated on one side only, the required descriptive term shall include the notation “(one side only).”

(10) The word “pad” shall be included in the descriptive term only when a hair or fiber filling material has been processed into pad forms.

(b) Cotton.

(1) “Staple cotton” means the staple fibrous growth as removed from the cotton seed in the usual process of ginning (first cut) containing no foreign material. The term “cotton” by itself shall not be used.

(2) The terms “cotton card strips,” “cotton comber,” “cotton fly,” “cotton picker,” “cotton noils” and “cotton motes” may be used to describe these cotton by-products removed by the various machine operations necessary in the manufacture of cotton yarn up to, but not including, the process of spinning. If the exact name of the cotton by-product is not used, such material shall be described as “cotton fiber.”

(3) “Cotton linters” shall be used to describe the fibrous growth removed from cotton seed subsequent to the usual process of ginning. The term “linters” alone shall not be used.

(4) The terms “blended cotton felt” or “cotton felt” are acceptable for the description of mixture of cotton by-products, up to the process of spinning, that are further processed by a garnett machine.

(c) Wool.

(1) “Wool” or “virgin wool” means the fleece of sheep or lambs, which has been scoured and carbonized or scoured. It shall not be the by-product of any process of manufacturing nor shall it have sustained prior use. It shall be free from kemp and vegetable matter or other foreign material.

(2) The terms “wool drawing laps,” “wool card waste,” “wool card strips” and “wool doffer waste,” shall be used to designate new wool fibers removed from the various machine operations necessary in the manufacture of wool yarn up to but not including the process

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of spinning and shall include noils, fulling flocks, wool pills and shank and tag wools. If the appropriate mill term is not used, the material shall be described as “wool fiber wastes.”

(3) “Tanners wool” means wool reclaimed from tanned sheepskin.

(4) “Wool felt” or “virgin wool felt” means wool fiber that meets the requirements of the definition of “wool” or “virgin wool” and has been further processed by a garnett machine.

(5) “Blended wool felt” means mill wastes from the various manufacturing operations, up to but not including the process of spinning, that has been further processed by a garnett machine.

(6) All material having the term “wool” in its approved name shall contain not less than ninety-five per cent wool fibers.

(d) Feathers and down.

(1) “Down” means the soft undercoating of waterfowl consisting of the light fluffy filaments grown from one quill point but without any quill shaft. This term shall be combined with the name of the water fowl from which obtained, together with the color of the down, e.g. “white goose down,” “grey duck down,” etc.

(2) “Down fiber” means the barbs of down plumes separated from the quill points and such term shall be combined with the kind and color of the water fowl from which obtained.

(3) “Feathers” means the appendages growing out of the skin of birds. This term shall be combined with the name and color of the bird from which obtained.

(4) “Feather fiber” means the barbs of feathers separated by any process from the quills, but free from quills. The name and color of the bird from which it is obtained shall be combined with this term.

(5) “Stripped feathers” means the feather barbs stripped from the main stem or quill but not to the extent of separating the barbs into feather fiber. The term “stripped feathers” shall also be combined with the name and color of the bird from which obtained.

(6) “Crushed feather” means feathers which have been processed through a so-called curling machine that has changed the original form of the feather, but has not removed the quill. This term shall also be combined with the name and color of the bird from which obtained and the percentage of each kind of crushed feathers shall be given, in the order of predominance, if the crushed feathers are part of a mixture.

(7) “Chopped feathers” means feathers which have been processed through a chopping machine which has cut the feathers into small pieces. The name and color of the bird from which they are obtained shall be combined with this term. If part of a mixture, such chopped feathers shall be indicated in the order or predominance and percentages stated.

(8) “Broken feathers” shall be so described, together with the name and color of bird from which obtained and the percentage, if the amount of broken feathers exceeds ten per cent of the feather content.

(9) The term “quill” means the main shaft or axis of a feather.

(10) The term “quill feather” means a wing feather or tail feather and shall be combined with the name and color of the bird from which obtained.

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(11) Feather mixtures shall be designated by name, color, character and percentage of each kind present in the mixture or the entire mixture shall be designated by the name of the lowest grade material used together with the color of the mixture. The grades of material in descending order are as follows: Goose down, duck down, goose feathers, duck feathers, turkey feathers, chicken feathers.

(e) **Hair.**

(1) "Hair" means the coarse, filamentous epidermal outgrowth of such animals as horses, cattle, hogs and goats. When used in the manufacture of upholstered furniture, bedding or filling material, hair shall be clean, properly cured, free from epidermin, excreta, or foreign or objectionable substances or odors. In addition to the word "hair," the tags shall also indicate from what kind of animal the hair originates, and its condition or appearance as hereinafter described.

(2) "Horse hair" means the strands of hair from the mane or tail of horses and shall be further described as "horse tail hair" or "horse mane hair."

(3) "Cattle hair" means the strands or filaments of hair from the body or tail of cattle and shall be further described as "cattle tail hair" or "cattle body hair."

(4) "Hog hair" means the bristle or body hair of swine.

(5) "Curled hair" means any hair that has been curled. The appropriate designation shall appear on the tag preceded by the word "curled."

(6) The term "shredded rubberized hair" means new rubberized hair that has been processed through a shredding machine. The term "curled" is not permitted in connection with shredded hair.

(f) **Rubber.**

(1) The term "rubber" shall apply to the following synthetic rubberlike materials as well as to natural rubber: Chloroprene, styrene-butadiene copolymers, butadiene-acrylonitrile copolymers, polymerized isobutylene, with or without comonomers present, and thioplasts (any of the polysulfide rubbers consisting of organic radicals linked through sulfur). Use of the term "rubber products" is not permitted on the tag.

(2) "Sponge rubber" means sponge products made from rubber which have previously been coagulated or solidified. "Sponge rubber" shall be indicated on the tag as follows: (a) "Sponge rubber." The use of this term shall be mandatory for a sponge rubber product consisting of not more than two inserts of unlaminated prime material for attaining desired height, nor more than one vertical splice in every three square feet of top surface area excluding those permitted for T's and U's, and not more than one splice in every three linear feet of added side-walls or in lieu thereof in each corner, excepting side-walls that are irregular in contour in which case the number of splices shall be subject to the approval of the labor department. (b) "Molded sponge rubber." The use of this term may be applied to a sponge rubber product which has been molded in the form in which it is intended to be used. (c) "Sponge rubber pieces." This term shall apply to a sponge rubber product which consists of mere pieces or otherwise fails to conform to the requirements for "sponge rubber" but shall not apply to sponge rubber which has been subjected to a shredding

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process. (d) “Cemented sponge rubber pieces.” The use of this term may be applied to sponge rubber pieces which have been cemented together. (e) “Shredded sponge rubber.” This term shall be applied to sponge rubber which has been subjected to a shredding process. (f) “Cemented shredded sponge rubber.” This term may be applied to shredded sponge rubber which has been cemented together.

(3) “Latex foam rubber” means a foam product made from rubber latex which previously has not been coagulated or solidified. “Latex foam rubber” shall be indicated on the tag as follows: (a) “Latex foam rubber.” The use of one of the terms set forth below shall be mandatory for a latex foam rubber product consisting of not more than two inserts of unlaminated prime material for attaining desired height, not more than one vertical splice in every three square feet of top surface area, except for T’s and U’s, but not more than two vertical splices regardless of top surface area excluding those permitted for T’s and U’s, and not more than one vertical splice in every three linear feet of vertical side-walls or in lieu thereof in each corner, excepting side-walls that are irregular in contour in which case the number of splices shall be subject to the approval of the labor department. (b) “Molded latex foam rubber.” The use of this term may be applied to a latex foam rubber product which has been molded in the form in which it is intended to be used. (c) “Latex foam rubber pieces.” This term shall apply to a latex foam rubber product which consists of mere pieces or otherwise fails to conform to the requirements for “foam rubber,” but shall not apply to foam rubber which has been subjected to a shredding process. (d) “Cemented latex foam rubber pieces.” The use of this term may be applied to latex foam rubber pieces which have been cemented together. (e) “Shredded latex foam rubber.” This term shall be applied to latex foam rubber which has been subjected to a shredding process. (f) “Cemented shredded latex foam rubber.” This term may be applied to shredded foam rubber which has been cemented together.

(4) The term “foam” without the word “rubber” means a polymerized material consisting of a mass of thin-walled cells produced chemically or physically and such non-rubber shall be designated on the tag as “foam,” together with the name of the organic base from which it is made, e.g., “urethane foam,” “vinyl foam.”

(5) The term “urethane foam” or “polyurethane” may be applied to a cellular urethane product which is created by the interaction of an ether or an ester and a carbamic acid derivative. If the foam is of the ether type, it may be designated as “polyether foam.” If the foam is of the ester type, it may be designated as “polyester foam.”

(6) The term “polystyrene foam” shall be applied to foam produced during the polymerization of a styrene monomer.

(7) The term “vinyl foam” shall be applied to a foam produced from vinyl.

(8) The term “molded” may precede the terms set forth above whenever such foam product has been made in a mold in the shape in which it is intended to be used.

(9) The term “pieces” follows the terms set forth in subdivision (4) of this subsection whenever the foam product consists of mere pieces or otherwise fails to conform to the requirements set forth in subdivision (3) above, but does not apply to a foam product which

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has been subjected to a shredding process.

(10) The term “shredded” shall precede or follow the terms set forth above whenever the foam product has been subjected to shredding process.

(11) The term “cemented” shall be applied to a shredded foam which has been cemented together, e.g., “cemented shredded urethane foam.”

(12) When a fabric-topped foam product or sponge used as a cover for an article of bedding is in excess of ten per cent of the weight of the entire filling material, it shall be disclosed on the tag and its percentage given.

(13) The term “polyester foam” means a foam produced by a polymerized reaction product of esters (i.e., a compound formed by the replacement of the acid hydrogen of an acid, organic or inorganic, by a hydro-carbon radical).

(14) The term “polyether foam” means a foam produced by a polymerized reaction product of ethers (i.e., hydro-carbons in which one or several hydrogen atoms are replaced by alkoxy groups).

(g) **Synthetic fibers.**

(1) “Acetate fiber” is a specific term used for man-made fibers, monofilaments and continuous filament yarns composed of acetylated cellulose, with or without lesser amounts of non-fiber-forming material. The term “acetate fibers” or the term “cellulose acetate fibers” shall be used for filling materials made of acetate.

(2) The term “rayon fiber” is a generic term for man-made fibers, monofilaments and continuous filament yarns composed of regenerated cellulose, with or without lesser amount of non-fiber-forming materials. The term “rayon fibers” shall be used to designate man-made fibers composed of regenerated cellulose.

(3) Synthetic fibers (other than acetate and rayon). When different long-chain synthetic polymers and/or copolymers are joined either chemically or physically to form a filament or fiber, a disclosure of the polymers and/or copolymers contained therein shall be made in the descending order of their percentage in the fiber by weight, e.g., “polystyrene fibers,” “vinyl-acrylic fibers.”

(4) The term “acrylic fibers” shall be used for a long-chain synthetic polymer which contains not less than eighty-five per cent acrylonitrile and which is formed into a filament.

(5) “Azlon fiber” is a generic term for fibers or filaments manufactured from modified proteins or derivatives thereof, with or without lesser amounts of non-fiber-forming materials. The term “azlon fiber” or “protein fibers” shall be used to designate fibers manufactured from azlon.

(6) “Nylon fiber” is a generic term for any long-chain synthetic polymeric amide which has recurring amide groups as an integral part of the main polymer chain, and which is capable of being formed into a filament in which the structural elements are oriented in the direction of the axis. The term “nylon fibers” shall be used to designate fibers manufactured from nylon.

(7) The term “polyethylene fibers” shall be used to designate fibers made from polymers and/or copolymers of ethylene.

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(8) The term “polyester fiber” means a fiber produced by a polymerized reaction product of esters (i.e., a compound formed by the replacement of the acid hydrogen of an acid, organic or inorganic, by a hydrocarbon radical).

(9) The term “polyether fiber” means a fiber produced by the polymerized reaction product of ethers (i.e., hydrocarbons in which one or several hydrogen atoms are replaced by alkoxy groups).

(10) The term “polystyrene fiber” shall be applied to the fibers resulting from the polymerization of styrene monomers.

(11) The term “polyvinylidene fiber” means fibers produced by the copolymer of vinylidene chloride and other monomers.

(12) The term “vinyl” shall be applied to homopolymers or copolymers of vinyl chloride.

(13) The term “vinyl fibers” shall be used to designate fibers or filaments manufactured from vinyl.

(h) Miscellaneous filling materials.

(1) “Cat-tail plant fibers” shall be so designated on the tag.

(2) “Cellulose and/or wood fiber” means fibers reduced from wood or other vegetable growth to a cellulose or fibrous state, and shall be described as “cellulose fiber” or “wood fiber.”

(3) “Coco husk fiber” means the fibrous growth obtained from the husk of the coconut.

(4) “Excelsior” means shredded threadlike wood fibers, and shall not include waste products such as shavings, sawdust or similar waste.

(5) “Flax tow” means the course, broken and refuse parts of flax separated from the fine fibrous parts in preparing the fibers for spinning.

(6) “Fur fiber” means the fine, soft under fur, with or without the usual guard hair, removed from the tanned or untanned pelt of animals of the class of furbearers. The name of the animal may be stated and when so indicated on the label shall be a true statement.

(7) “Glass fiber” means the very fine filaments or fibers made of glass.

(8) “Hay” means any grass, properly dried or cured, free from dust, burrs, sticks or other objectionable material.

(9) “Jute fiber” means the fiber derived from any species of the *Corchorus* plant.

(10) “Jute tow” means the broken and refuse parts of jute separated from the fibrous parts in preparing the fibers for spinning.

(11) “Kapok” means the mass of fibers investing the seed of the Kapok trees (*Ceiba Pentandra*). Any additional term descriptive of the geographical origin or of the quality of such fibers shall be a true statement when set forth on the tag.

(12) “Milkweed fiber” means the surface fiber from the inside of the seed pods of milkweed plants (*Asclepias*).

(13) “Moss” means the vegetable fibers processed from the moss growth found in swamps and on trees.

(14) “Palm fiber” means the fibrous material obtained from the leaf of a palm, palmetto or palmyra tree.

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(15) “Silk fiber” means silk filaments or fibers, including the by-products of any manufacturing or preparing operation up to but not including spinning.

(16) “Sisal fiber” means the leaf fiber derived from the “Agave Sisalana” and similar species of Agaves.

(17) “Sisal fiber tow” means the residual fibers left after the extraction of the spinnable sisal fiber from the leaf. For the purpose of these regulations, this includes the products known as “Bagassi.” It shall not contain over three per cent pulp.

(18) “Fiber pads” means a fiber interwoven or punched on burlap or any other woven material or otherwise fabricated into a pad, and when the term “fiber pad” is used, the name of the fiber as herein defined shall be included.

(19) “Tula fiber” means the leaf fiber derived from the “Tula Istle” and similar species of agaves.

(20) “Straw” means the stalk or stem of grain, such as wheat, rye, oats, rice, and the like, after threshing. The kind of straw may be stated, but when indicated shall be a true statement. It shall be free from beards, chaff, bristles, husks, glumes, dirt or extraneous matter.

(21) “Sea grass” means any material obtained from maritime plants or seaweeds.

(22) “Shoddy” means any material created from the processing of secondhand materials, clothing or used rags.

(Effective July 27, 1984)

Sec. 21a-235-9. Cleansing and sterilization of materials required

The bedding and upholstered furniture laws require the cleansing and sterilization of all articles and materials that have become soiled or contaminated in any manner or that come from an animal or fowl or that are infested with germs of any kind or that are unsanitary or that are second-hand. This provision includes all mill wastes, scraps, clippings and other wastes of manufacture which have become soiled or contaminated by falling upon the floor or in any other manner. All sterilization shall be in full compliance with the specifications regarding sterilization promulgated under the authority of section 21a-235 of the general statutes.

(See. G.S. § 21a-232 (a), (b), (f).)

(Effective July 27, 1984)

Sec. 21a-235-10. Sterilization permit

Each person who undertakes to do sterilizing work shall secure a sterilization permit which requires a detailed description of the processes to be employed and the payment of a twenty-five dollar license fee.

(See. G.S. § 21a-232 (m).)

(Effective July 27, 1984)

Sec. 21a-235-11. Records of permit holders

Each person to whom a sterilization permit is issued shall keep an accurate record of the

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name and address of each person other than the holder of such permit for whom sterilization is done, together with the kind and amount of articles and/or materials sterilized and the date of such sterilization. All records shall be open at all times during business hours for examination by the commissioner or by inspectors of the department, and certified copies of such records shall be furnished to the department not later than the fifth of each month, covering the preceding month.

(See G.S. § 21a-232.)

(Effective July 27, 1984)

Sec. 21a-235-12. Sterilization in own plant or by permit holder. Cooperative sterilization plants

(a) A maker or vendor of second-hand articles or materials, or new materials that have been contaminated, may sterilize such articles or materials in his own approved plant or have them sterilized by any concern having a sterilization permit. The permit number of the approved process shall be printed or stamped on each tag attached to any sterilized article or material.

(b) Persons who do a small amount of business in remaking, renovating or selling second-hand furniture may not wish to set up a sterilization plant and to pay the twenty-five dollar annual fee for a sterilization permit. Such small operators and dealers may get sterilization done by a commercial plant or may band together to set up a cooperative sterilization plant to take care of their needs.

(Effective July 27, 1984)

Sec. 21a-235-13. Sterilization of new materials of animal origin

Any process used for cleaning and curing feathers, cleaning and curling hair, cleaning wool, or cleaning or curing any other material derived from an animal or fowl, shall not be deemed to afford proper and thorough sterilization unless such process effectually removes all disease spores, germs and bacilli, all insects and insect nits, all animal matter subject to decay and all manner of dirt and filth.

(a) **New feathers.** Application for a sterilization permit shall show that feathers are thoroughly washed and rinsed and that live steam and dry heat are applied. The product shall pass all tests for cleanness and freedom from nits and germs.

(b) **New hair.** Application for a sterilization permit shall show the entire process used for washing and curling (if curled) and that at some point during the process the hair remains in live steam or boiling water a sufficient period to kill all dangerous spores and germs.

(c) **New wool.** Application for a sterilization permit shall indicate whether raw wool or previously scoured and carbonized wool is to be treated. Processes for raw wool shall be set forth in detail and indicate that the wool has been subjected to steam or boiling water for a sufficient time to kill all dangerous spores and germs.

(See Reg. § 21a-235-18.)

(Effective July 27, 1984)

Sec. 21a-235-14. Sterilization of second-hand articles and materials

The law requires that all second-hand articles or materials of bedding or upholstered furniture shall be sterilized and properly labeled before they are offered for sale or returned to the owner to be offered for sale or to be used by him in any way. This provision is necessary for the protection of those who remake and renovate such articles and materials, as well as those who use them. Each such sterilized second-hand article or material shall bear a yellow tag giving the materials, the date of sterilization and the name of the vendor or owner.

(See G.S. § 21a-232.)

(Effective July 27, 1984)

Sec. 21a-235-15. Sterilization before use

All second-hand materials and all new materials which have been exposed to contamination shall be sterilized before being put through a picker or a gar-netting machine.

(Effective July 27, 1984)

Sec. 21a-235-16. Renovation of second-hand furniture

(a) **Furniture renovated or remade.** Each complete article of furniture shall be sterilized before being renovated or remade. If sterilization by steam or chemical spray would spoil the finish on the frame of an article of upholstered furniture, sterilization may be done by applying the sterilizing agents by hand. The frame, when so sterilized shall be labeled with a yellow tag stating that the frame is secondhand. New springs and new filling materials attached as a part of the frame shall be designated as new on the yellow tag attached to the frame. Each cushion, pillow or other separate part, made entirely of new materials, shall be labeled with a white tag stating that such part is new and giving the kinds and percentages of all filling materials.

(b) **Coverings or filling materials reused.** All coverings and filling materials which are to be used again in renovating or remaking any article of furniture shall be sterilized by steam, hot air or approved chemical agents. Fine fabrics which would be spoiled by wetting may be sterilized by hot air. All coverings or filling materials, so sterilized, shall be labeled as second-hand when resold.

(Effective July 27, 1984)

Sec. 21a-235-17. Storage of unsterilized articles

All unsterilized second-hand articles or materials shall be separately stored and completely segregated from new or clean articles or materials. No new or clean materials shall be kept or stored within a room or space used for sterilizing secondhand materials. Sterilizing chambers shall not be used for storage purposes.

(Effective July 27, 1984)

Sec. 21a-235-18. Sterilization processes

“Sterilization,” in reference to chapter 420a of the general statutes, means the destruction of all bacilli and spores of bacilli as well as insects and insect eggs (nits). Only those processes and agencies which destroy all disease germs, insects and insect eggs shall be accepted as effective sterilization processes or agencies under the law. There are five effective sterilization processes recognized: (1) Live steam under pressure; (2) live steam streaming from a boiler carrying not less than fifteen pounds pressure; (3) boiling water; (4) hot air, and (5) caustic solution of standard strength for sterilizing metal articles and parts. The types of apparatus and processes described below are accepted sterilizers and, when shown to be effective, shall be approved by the commissioner.

(a) **Steam pressure.** The most efficient process of sterilization is the steam pressure process when properly applied. Live steam, applied in a steam tight chamber from which the air has been expelled so as to penetrate to all parts of any article or material treated, and maintained at a pressure of at least fifteen pounds per square inch and a temperature of at least 250°F. at the point of lowest temperature for a period of not less than thirty minutes is an effective sterilizer. If the pressure is maintained at twenty pounds per square inch, the time of treatment may be reduced to twenty minutes. The articles or materials treated shall be placed on racks so as to allow free access of steam to all surfaces and parts. Materials treated shall not be compacted or compressed to a density greater than that of ordinary cotton felt used for filling material. The sterilizing chamber shall be strong enough to withstand the pressure indicated and shall be equipped with a standard steam gauge plainly visible at all times from the working floor. Temperature control shall be maintained by means of a recording temperature gauge. A Diac sterilizer control or equally effective control may be used until a recording temperature gauge can be installed.

(b) **Streaming steam.** A stream of live steam applied to articles or materials in the condition described above is acceptable as a sterilizing process, provided the steam shall have a temperature of at least 212°F. and shall be applied for a period of not less than three hours. Streaming steam may be used in two applications of one and one-half hours each with an interval of six hours but not more than twenty-four hours between each application. The steam chamber shall be steam tight with outlet valves at top and bottom which shall be kept open to prevent pressure in the chamber. Condensed steam shall be drawn off.

(c) **Boiling water.** Boiling water is acceptable as a sterilizing process if uncompacted materials are immersed in it for a period of not less than two hours.

(d) **Hot air.** Hot air may be accepted as a sterilizer under proper conditions although it is not as effective as steam or boiling water. A hot air sterilizing process to be approved by the commissioner shall safely produce a temperature of 250°F. at the point of lowest temperature in the chamber. Temperature shall be automatically controlled and shall be maintained for a period of at least two and one-half hours. Temperature shall be generated by means of properly guarded electric heating units or by steam pipes carrying live steam. An indirect gas heating system may be used if the material cannot be ignited by the gas flame. Hot air may be used for sterilizing material which is not compressed to a degree in

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excess of the customary compression of cotton felt. Articles shall be so spaced as to allow free circulation of hot air.

(e) **Caustic soda.** For sterilizing second-hand metal used in springs, cribs, cots, etc., the commissioner will approve a caustic solution of one-half pound of caustic soda (76% sodium hydroxide) to each gallon of water. The solution shall be used in a tank impervious to the action of the solution and of sufficient size to permit the complete submersion of material. Metal shall remain in a cold solution for a period of at least twenty-four hours but, if the solution is kept at the boiling point, this period may be reduced to three hours. In using such caustic process, all plugs and obstructions shall be removed so as to permit free passage of the solution to the inside of all tubing and to all other parts. After sterilization all metal articles shall be thoroughly washed with clean water until all of the caustic solution is removed.

(f) **Chemical sterilization.** An approved chemical germicide may be used under proper conditions.

(Effective July 27, 1984)

Sec. 21a-235-19. Chemical sterilization: Temperature of sterilization room or chamber

Chemical reactions are hastened and made more complete by high temperatures. For the most satisfactory sterilizing results, a temperature range of 75° to 110° is desirable. In no case should the temperature be allowed to fall below 75°F. during the period of sterilization.

(Effective July 27, 1984)

Sec. 21a-235-20. Period of exposure for complete destruction of bacteria, spores, insects and insect eggs

The period of exposure for complete chemical sterilization is arrived at by adding to the time required to destroy germs by formaldehyde one-half the time required by any given insecticide to kill insects and insect eggs. In no instance shall the total time for complete sterilization be less than the time required by the given insecticide to kill all insect life. The periods of exposure required for complete sterilization with formaldehyde and each of the listed insecticides are given below. The temperature in all cases shall be not less than 75°F.

(a) **Ethylene oxide and carbon dioxide (“carboxide”).** If three pounds of this chemical mixture per one thousand cubic feet are used, the exposure time shall be one-half of twelve hours exposure to the insecticide, plus ten hours exposure to formaldehyde, a total of sixteen hours. If five pounds per one thousand cubic feet are used, the time of exposure shall be one-half of eight hours for the insecticide plus ten hours for formaldehyde or fourteen hours all told.

(b) **Hydrocyanic acid gas.** To be used only by licensed operatives. Exposure time for hydrocyanic acid gas, six hours plus ten hours for formaldehyde or sixteen hours all told.

(c) **Methyl formate and carbon dioxide (“malium”).** Six hours plus ten hours total sixteen hours.

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(d) **Ethylene dichloride and carbon tetrachloride.** Fourteen hours plus ten hours, total twenty-four hours.

(e) **Carbon tetrachloride.** Fourteen hours plus ten hours, total twenty-four hours.

(f) **Sulphur dioxide.** Ten hours plus ten hours, total twenty hours.

(g) **Dichloro-diphenyl-trichloroethane (DDT).** Six hours plus ten hours for formaldehyde treatment, total sixteen hours.

(For quantities of chemicals, see Regs. 21a-235-23, 21a-235-24.)

(Effective July 27, 1984)

Sec. 21a-235-21. Steam, water and hot air as sterilizers

Live steam under pressure, live streaming steam, boiling water, and hot air at a temperature of not less than 212°F. are both germicides and insecticides. All articles and materials which are susceptible of treatment by any of these methods need no further treatment to render them free of all germs and insect life. Dry hot air is not so effective as steam or boiling water in killing either germs or insects. Hence, hot air chambers shall be kept at 250°F. for a period of two and one-half hours to insure complete sterilization. Steam at pressure of fifteen pounds per square inch giving a temperature of 250°F. is effective with an exposure of thirty minutes; at pressure of twenty pounds (temperature of about 300°), the time is twenty minutes. Streaming steam at a temperature of not less than 212°F. is fairly effective with an exposure of three hours. Boiling water is effective with two hours of exposure.

(Effective July 27, 1984)

Sec. 21a-235-22. Maintenance of apparatus

All rooms, chambers, containers autoclaves, tanks, boilers, ducts, valves, gauges, heaters and all auxiliary equipment necessary or incidental for the proper sterilization of articles, filling materials or metal shall be clean and maintained at all times in good repair and in proper working condition.

(Effective July 27, 1984)

Sec. 21a-235-23. Fumigation: Germicides

(a) Formaldehyde is in common use and is accepted as a germicide (not an insecticide). The commissioner shall permit the use of a proper formaldehyde process until further notice, provided this process is used in conjunction with an approved insecticide process. (See section 21a-235-20.)

(b) When approved by the commissioner, formaldehyde gas in the presence of moisture may be used for treating either loose materials or complete articles when the filling is not compressed to a degree in excess of the usual compression of cotton felt. Articles shall be so spaced as to allow free circulation of gas. The exhaust from the sterilizing room or cabinet shall be carried by a duct or a chimney flue extending above the roof of the building.

(c) Formaldehyde gas generated from one pint of formaldehyde solution (United States

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Pharmacopoeia standard) for each one thousand cubic feet of space in the sterilizing chamber is acceptable. Materials shall be treated with formaldehyde gas and moisture for at least ten hours. The minimum quantity of solution permitted is two ounces, regardless of how small the sterilizing chamber is. The solution shall be heated or boiled to release the gas. The safest and most convenient way to do this is to add to the solution one-half its weight of potassium permanganate. This boils the solution and releases the gas. To avoid boiling over, the mixing should be done in a large pail. The gas shall be disseminated throughout the chamber so as to reach all parts of the materials treated. Sufficient moisture in the chamber may be produced by thoroughly sprinkling the floor of the chamber with warm water before commencing to sterilize. The room shall be gas tight and equipped with air inlet and outlet. (An exhaust fan will greatly facilitate the removal of dead gases and fumes after sterilization is completed.) Tight closure gates or valves shall be provided for both inlet and outlet. Shelves shall be of lattice construction. This process is not suitable, and shall not be approved, for complete sterilization of any materials or articles. For complete sterilization, an approved insecticide shall be used in addition to formaldehyde.

(Effective July 27, 1984)

Sec. 21a-235-24. Fumigation: Insecticides

The following substances and processes are approved as insecticides for use with formaldehyde or any accepted germicide.

(a) **Ethylene oxide and carbon dioxide: "Carboxide."** A mixture of one part ethylene oxide at ordinary temperatures is a colorless gas with a faint odor of ether. At 50°F. it is a mobile colorless liquid. Concentrated vapors of ethylene oxide are inflammable or explosive. To overcome the fire and explosion hazard, carbon dioxide is added. This eliminates these hazards and about doubles the toxicity of the ethylene oxide gas to insects. Ethylene oxide gas penetrates deeply into articles and materials of bedding and upholstery and destroys insects and insect eggs effectively. It is not very toxic to man. "Carboxide" gas is nonexplosive and noninflammable and does not injure fabrics or furniture. The materials to be treated shall be placed in a gas tight chamber on open lattice racks so as to allow the free access of the gas to the materials. The gas should be released into the chamber in the form of a mist or spray. Three pounds of ethylene oxide-carbon dioxide (or "carboxide") per one thousand cubic feet in a gas tight chamber at a temperature of 75°F. will destroy insects and insect eggs in twelve hours; five pounds per one thousand cubic feet is effective in eight hours.

(b) **Hydrocyanic acid gas.** This gas is very dangerous as it is deadly poisonous to man and should be used only by expert operators, licensed by the local health authorities. (See Reg. 21a-235-29.)

(c) **Methyl formate and carbon dioxides: "Malium."** This is a noninflammable liquid consisting of fifteen parts methyl formate and eighty-five parts carbon dioxide by weight. Have air tight room, except for vent pipe to go above roof. Release gas by connecting cylinder to a manifold outside the room with a discharge pipe to the inside room. Moisture

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in the room is undesirable. Keep the temperature in room at not less than 75°F. Means shall be provided for exhausting vapors after fumigation. Outlet should be above roof. Clear the room of gas before opening the door after fumigation.

(d) **Ethylene dichloride and carbon tetrachloride.** This is a noninflammable liquid mixture of seventy-five per cent of the former and twenty-five per cent of the latter by volume. Ethylene dichloride is inflammable, but the mixture with carbon tetrachloride is not. Use a gas tight room. Place liquid in a shallow trough not more than two and one-half inches deep. Hang it about eighteen inches below the ceiling. The gas is heavy and travels downward. Use not less than fourteen pounds (five quarts) per one thousand cubic feet of air space in the room. Keep the temperature of room at not less than 75°F. nor more than 90°F. Moisture in the room is undesirable. Means shall be provided for exhausting vapors after fumigation. Outlet should be above the roof. Clear the room of gas before opening the door after fumigation.

(e) **Carbon tetrachloride.** Carbon tetrachloride is a thin, transparent, colorless, noninflammable liquid with an odor like chloroform. It is used as a fire extinguisher. Use an air-tight room equipped with a ventilating pipe which leads to a point above the roof. Have a gas-tight valve in the vent pipe. Place the tetrachloride in an open shallow pan at the top of the room. The gas is heavy and travels downward. The liquid evaporates on exposure to air. Use eight pounds per one thousand cubic feet of room space. Keep the temperature of the room at not less than 75°F. Clear the room of gas before opening the door after fumigation.

(f) **Sulphur dioxide.** This is sulphur fumes. The cheapest and simplest method of producing these fumes is the “pot” method. Use broad, shallow pots to assure rapid production of fumes. Use enough pots so that sulphur may be spread to a thickness of not more than two inches. Provide alcohol to start the sulphur burning. Provide a gas-tight room with fresh air inlet and exhaust pipe to outer air above the roof. Have tight valves in each pipe. Use one pound of sulphur to each one thousand cubic feet of room space. There is danger of fire from burning sulphur. Set the pots on brick or metal supports in a large pan of water. These fumes have a bleaching effect and also will tarnish metal. To light the sulphur quickly, sprinkle with alcohol and throw a lighted match in the pot. Keep the room dry—moisture is undesirable during fumigation. Clear the room of gas after the fumigation period before opening room door.

(Effective July 27, 1984)

Sec. 21a-235-25. Application of insecticides and germicides

Approved insecticides and germicides may be applied in either of two ways: (1) They may be applied in the form of a gas generated in a properly constructed gas tight vault or chamber; or (2) they may be applied with an approved spraying device.

(Effective July 27, 1984)

Sec. 21a-235-26. Temperature of germicides and insecticides

Any chemical germicide or insecticide acts more quickly and effectively at high temperatures. A temperature range from 75°F. to 110°F. is desirable. In no case shall the temperature be allowed to fall below 70°F.

(Effective July 27, 1984)

Sec. 21a-235-27. Use of gas

If sterilization or fumigation is to be effected with gas, a properly constructed gas tight vault or chamber shall be installed.

(Effective July 27, 1984)

Sec. 21a-235-28. Formaldehyde gas

If formaldehyde is applied in gaseous form, the full strength standard U.S. Pharmacopoeia solution shall be used undiluted. The formaldehyde gas is generated by boiling this solution. The most satisfactory way of generating the formaldehyde gas is to add one-half its weight of potassium permanganate.

(Effective July 27, 1984)

Sec. 21a-235-29. Poisonous gas

Those who desire to use hydrocyanic gas or any other poisonous gas as an insecticide shall secure the approval of the local health officers before installing the chamber or vault for the use of such processes.

(Effective July 27, 1984)

Sec. 21a-235-30. Spraying

(a) Certain insecticides may be applied by direct spray or mist spray methods. When these insecticides are effective, they may be approved and used. The germicides and insecticides listed in these specifications are intended merely to indicate the properties and types of chemicals and processes requisite for proper sterilization. The list is not intended to be complete. Any germicide or insecticide not on the list which shall be shown to destroy germs or insects effectively under reasonable conditions without involving any serious hazards will be approved by the commissioner and added to the list.

(b) Two methods of applying chemical germicides and insecticides by means of a spray are permissible: (1) Direct spraying. The material or article shall be placed in a separate, closed room or chamber which shall be quite tight, but need not be gas tight. Either a good hand sprayer or a power sprayer may be used to spray the chemicals on the materials or articles. The materials or articles shall be thoroughly wetted with the chemical solution on all surfaces. The amount of chemicals used shall be approximately the same as would be required in the fumigation process for the same materials or articles; (2) The mist spray method. A gas-tight chamber shall be used. The chemicals are released from container tanks and are sprayed into the sterilizing chamber by an atomizer spray in the form of a mist. The

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amount of chemicals used shall be the same as that required for the same articles to be sterilized by fumigation.

(c) When germicide or insecticide is applied with a spray, a separate room shall be provided and isolated from other parts of the establishment. The material or article shall be thoroughly sprayed over all surfaces and in all crevices and corners.

(Effective July 27, 1984)

Sec. 21a-235-31. Formaldehyde spray

(a) If formaldehyde is applied with a spray, the standard U.S. Pharmacopoeia solution shall be diluted with three parts of water to one part of solution. This gives a ten per cent formaldehyde solution which is sufficient to kill all active germs which come in contact with the solution. (This ten per cent solution will not injure or fade fabrics.)

(b) If formaldehyde solution is applied with a spray, the operator shall wear rubber gloves and a mask to protect hands and eyes against the irritating effects of this solution.

(Effective July 27, 1984)

Sec. 21a-235-32. “Off sale” articles

The commissioner or a representative of the commissioner may order “off sale” and so tag any article of bedding, upholstered furniture or material therefor not tagged or labeled as required by these regulations or which in any other respect does not conform with the requirements of statute or regulation issued under the authority thereof, and may take such other action as may be authorized by statute. No article or material so ordered “off sale” shall be sold or used, nor shall such materials or articles or contents thereof be altered or removed in whole or part, until such articles or materials are released by the commissioner or his authorized representative and the “off sale” tag removed. All articles or materials ordered “off sale” are subject to frequent examination and shall be so placed as to be readily accessible at all times for examination upon demand of the commissioner or his authorized representative.

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Subject

Designation of Controlled Drugs

Inclusive Sections

§§ 21a-243-1—21a-243-18

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Designation of Controlled Drugs

Sec. 21a-243-1. Volatile substances

(a) The following volatile substances are hereby designated as controlled drugs to the extent that said chemical substances or compounds containing said chemical substances are sold, prescribed, dispensed, compounded, possessed or controlled or delivered or administered to another person, with the purpose that said chemical substances shall be breathed, inhaled, sniffed or drunk to induce a stimulant, depressant or hallucinogenic effect upon the higher functions of the central nervous system: Acetone; toluol; trichloroethylene; isopropanol; methanol; ether; methyl cellosolve acetate; toluene; hexane; butyl alcohol; benzene; methyl ethyl ketone; cyclohexanone; pentochlorophenol; ethyl acetate; methyl isobutyl ketone; trichloroethane, and dichlorodifluoromethane.

(b) Insofar as it is the express intent of these regulations to provide medical treatment whenever possible, there is hereby created the presumption that one who is found to have inhaled or to be under the influence of the above-described volatile substances shall be deemed to be psychologically dependent upon said volatile substances.

(c) To the extent that it is possible, medical treatment rather than criminal sanctions shall be afforded individuals who breathe, inhale, sniff or drink the above-named volatile substances.

(Effective July 27, 1984)

Sec. 21a-243-2. Criminal liability of vendor

No vendor of the aforementioned volatile substances shall be deemed to have violated the provisions of chapter 420b of the general statutes insofar as sale, dispensing or delivering of one or more of said volatile substances or compounds containing said chemical substances is concerned, unless he knew or should have known of the improper purpose to which said substance was to be put.

(Effective July 27, 1984)

Sec. 21a-243-3. When volatile substances not controlled drug

The above drugs are designated as controlled drugs only for the limited purpose stated in section 21a-243-1. Insofar as substances containing said drugs are possessed, sold, dispensed, compounded or delivered for licit purposes, i.e., other than to produce a stimulant, depressant or hallucinogenic effect upon the higher functions of the central nervous system by breathing, inhaling, sniffing or drinking, such substances are expressly not controlled and neither the regulatory provisions, including but not limited to record keeping, licensing, and the writing of prescriptions nor the criminal sanctions and proscriptions of chapter 420b of the general statutes shall apply.

(Effective July 27, 1984)

Sec. 21a-243-4. Anesthesia

The breathing, inhalation, sniffing or drinking of anesthesia for medical or dental purposes under the direction of a physician, dentist or osteopath acting in the course of his professional practice, is determined to be a licit purpose and not in contravention of these regulations or the provisions of chapter 420b of the general statutes.

(Effective July 27, 1984)

Sec. 21a-243-5. Controlled drugs

The following substances are hereby designated as controlled drugs for all purposes of chapter 420b of the general statutes: *Datura stramonium*, *hyoscyamus niger*, *atropa belladonna* or the alkaloids atropine, hyoscyamine, belladonnine, apoatropine, or any mixture of these alkaloids such as daturine, or the synthetic homatropine or any salts of these alkaloids. Any drug or preparation containing any of the above-mentioned substances which is permitted by federal food and drug laws to be sold or dispensed without a prescription or written order shall not be a controlled drug.

(Effective July 27, 1984)

Sec. 21a-243-6. Amyl nitrate

Amyl nitrate is hereby designated as a controlled drug as defined under chapter 420b of the general statutes.

(Effective July 27, 1984)

Schedules of Controlled Substances

Sec. 21a-243-7. Controlled substances in schedule I

The controlled substances listed in this regulation are included by whatever official, common, usual, chemical, or trade name designation in Schedule I:

(a) Any of the following opiates, including their isomers, esters, ethers, salts and salts of isomers, esters and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation:

- (1) Acetylalpha-methylfentanyl;
- (2) Acetylmethadol;
- (3) Allylprodine;
- (4) Alphacetylmethadol (except Levo-alphacetylmethadol or LAAM);
- (5) Alphameprodine;
- (6) Alphamethadol;
- (7) Alpha-methylfentanyl;
- (8) Alphamethylthiofentanyl;
- (9) Benzethidine;
- (10) Betacetylmethadol;
- (11) Beta-hydroxy-fentanyl;

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- (12) Beta-hydroxy-3-methylfentanyl;
- (13) Betameprodine;
- (14) Betamethadol;
- (15) Betaprodine;
- (16) Clonitazene;
- (17) Dextromoramide;
- (18) Diampromide;
- (19) Diethylthiambutene;
- (20) Difenoxin;
- (21) Dimenoxadol;
- (22) Dimepheptanol;
- (23) Dimethylthiambutene;
- (24) Dioxaphetyl Butyrate;
- (25) Dipipanone;
- (26) Ethylmethylthiambutene;
- (27) Etonitazene;
- (28) Etoxidine;
- (29) Furethidine;
- (30) Hydroxypethidine;
- (31) Ketobemidone;
- (32) Levomoramide;
- (33) Levophenacilmorphan;
- (34) 3-methylfentanyl;
- (35) 3-methylthiofentanyl;
- (36) Morpheridine;
- (37) Noracymethadol;
- (38) Norlevorphanol;
- (39) Normethadone;
- (40) Norpipanone;
- (41) Para-fluorofentanyl;
- (42) PEPAP (1-(-2-phenethyl)-4-phenyl-4-acetoxypiperidine);
- (43) Phenadoxone;
- (44) Phenampromide;
- (45) Phenomorphan;
- (46) Phenoperidine;
- (47) Piritramide;
- (48) Proheptazine;
- (49) Properidine;
- (50) Propiram;
- (51) Racemoramide;
- (52) Thiofentanyl;

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- (53) Tilidine;
- (54) Trimeperidine.

(b) Any of the following opium derivatives, their salts, isomers and salts of isomers, unless specifically excepted whenever the existence of these salts, isomers and salts of isomers is possible within the specific chemical designation:

- (1) Acetorphine;
- (2) Acetyldihydrocodeine;
- (3) Benzylmorphine;
- (4) Codeine methylbromide;
- (5) Codeine-N-oxide;
- (6) Cyprenorphine;
- (7) Desomorphine;
- (8) Dihydromorphine;
- (9) Drotebanol;
- (10) Etorphine, except hydrochloride salts;
- (11) Heroin;
- (12) Hydromorphanol;
- (13) Methyldesorphine;
- (14) Methyldihydromorphine;
- (15) Morphine methylbromide;
- (16) Morphine methylsulfonate;
- (17) Morphine-N-oxide;
- (18) Myrophine;
- (19) Nicocodeine;
- (20) Nicomorphine;
- (21) Normorphine;
- (22) Pholcodine;
- (23) Thebacon.

(c) Any material, compound, mixture or preparation which contains their salts, isomers and salts of isomers, unless specifically excepted, whenever the existence of these salts, isomers, and salts of isomers is possible within the specific chemical designation:

- (1) Alpha-ethyltryptamine;
- (2) 4-bromo-2,5-dimethoxyamphetamine; or 4-bromo-2,5-DMA;
- (3) 2,5-dimethoxyamphetamine; or 2,5-DMA;
- (4) 2,5-Dimethoxy-4-ethylamphetamone or DOET;
- (5) 3,4-M ethylenedioxy-N-ethylamphetamine;
- (6) 1-methyl-4-phenyl-4-propionoxypiperidine; or MPPP;
- (7) 3,4-methylenedioxymethamphetamine; or MDMA;
- (8) 2,5-dimethoxy-4-(n)-propylthiopenenthylamine (2C-T-7);
- (9) 4-methoxyamphetamine; or PMA;
- (10) 5-methoxy-3,4-methylenedioxy-amphetamine;

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- (11) 5-Methoxy-nn-Diisopropyltryptamine(5-methoxy-dipt);
 - (12) 4-methyl-2,5-dimethoxyamphetamine; or DOM; or STP
 - (13) 3,4-methylenedioxy amphetamine; or MDA;
 - (14) N-hydroxy-3,4-methylenedioxyamphetamine (also known as N-hydroxy-alpha-methyl-3,4(methylenedioxy)phenethylamine, and N-hydroxy MDA;
 - (15) 3,4,5-trimethoxy amphetamine;
 - (16) benzylpiperazine or BZP;
 - (17) Bufotenine or Mappine;
 - (18) Alphaethyltryptamine;
 - (19) Diethyltryptamine or DET;
 - (20) Dimethyltryptamine or DMT;
 - (21) Ibogaine;
 - (22) Lysergic acid diethylamide;
 - (23) MDVP (3,4-methylenedioxyprovalerone);
 - (24) 3,4-methylenedioxy-N-methycathione (methylo)
 - (25) Mephedrone (4-methylmethcathinone);
 - (26) Mescaline;
 - (27) Parahexyl or Synhexyl;
 - (28) Peyote, meaning all parts of the plants;
 - (29) 1-(2-phenylethyl)-4-phenyl-4-acetoxypiperidine; or PEPAP;
 - (30) N-ethyl-3-piperidyl benzilate;
 - (31) N-methyl-3-piperidyl benzilate;
 - (32) Psilocybin;
 - (33) Psilocyn;
 - (34) Tetrahydrocannabinols except Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a United States food and drug administration approved product;
 - (35) Salvia divinorum;
 - (36) Salvinorin A;
 - (37) Ethylamine analog of phencyclidine, Cyclohexamine or PCE;
 - (38) 4-Bromo-2,5-dimethoxyphenethylamine;
 - (39) Pyrrolidine analog of phencyclidine, PCP or PHP;
 - (40) 1-[1-(2-thienyl)cyclohexyl]pyrrolidine;
 - (41) Thiophene analog of phencyclidine, TPCP or TCP;
 - (42) Tiletamine or 2-(ethylamino)-2-(2-thienyl)-cyclohexanone;
 - (43) Trifluoromethylphenylpiperazine or TFMPP.
- (d) Any material, compound, mixture or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, their salts, isomers and salts of isomers unless specifically excepted, wherever the existence of these salts, isomers and salts of isomers is possible within the specific chemical designation:
- (1) Gamma-hydroxy butyric acid, except if contained in a drug product for which an

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application has been approved under section 505 of the federal food, drug and cosmetic act;

- (2) Gamma-butyrolactone;
- (3) Mecloqualone;
- (4) Methaqualone; or
- (5) Zolazepam.

(e) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers:

- (1) Aminorex;
- (2) N-benzylpiperazine (some other names: BZP; 1-benzylpiperazine);
- (3) 4-Methylaminorex;
- (4) Cathinone;
- (5) Fenethylamine;
- (6) Methcathinone;
- (7) N-ethylamphetamine;
- (8) N,N-Dimethylamphetamine.

(f) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of a substance having a psychotropic response primarily by agonist activity at cannabinoid-specific receptors affecting the central nervous system. Specific compounds include, but are not limited to:

- (1) 1-pentyl-3-(1-naphthoyl)indole (JWH-018);
- (2) 1-butyl-3-(1-naphthoyl)indole (JWH-073);
- (3) 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200);
- (4) 5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (CP-47,497);
- (5) 5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol CP-47,497 C8 homologue).

(Effective July 23, 1987; Amended August 22, 1995; Amended March 6, 2000; Amended June 10, 2003; Amended June 10, 2011; Amended March 29, 2012; Amended September 17, 2013)

Sec. 21a-243-8. Controlled substances in schedule II

The controlled substances listed in this regulation are included by whatever official, common, usual, chemical, or trade name designation in Schedule II:

(a) Any of the following substances, except those narcotic drugs listed in other schedules, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by combination of extraction and chemical synthesis:

- (1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate excluding Apomorphine, Dextrorphan, Nalbuphine, Naloxone, Nal-trexone, and their salts, but including the following: Raw opium, opium extracts, opium fluid extracts, powdered opium, granulated opium, tincture of opium, codeine, dihydroetorphine,

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ethylmorphine, etorphine hydrochloride, hydrocodone, hydromorphone, metopon, morphine, oripavine, oxycodone, oxymorphone and thebaine;

(2) any salt, compound, isomer, derivative or preparation thereof which is chemically equivalent or identical with any of the substances referred to in paragraph (1), but not including the isoquinoline alkaloids of opium;

(3) opium poppy and poppy straw;

(4) coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, but not including decocainized coca leaves or extractions which do not contain cocaine or ecgonine;

(5) concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid or powder form which contains the phenanthrine alkaloids of opium poppy).

(b) Any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation, Dextrophan and Levopropoxyphene excepted:

(1) Alfentanil;

(2) Alphaprodine;

(3) Anileridine;

(4) Bezitramide;

(5) bulk Dextropropoxyphene (nondosage forms);

(6) Carfentanil;

(7) Dihydrocodeine;

(8) Diphenoxylate;

(9) Fentanyl;

(10) Isomethadone;

(11) Levo-alphaacetylmethadol or LAAM;

(12) Levomethorphan;

(13) Levorphanol;

(14) Metazocine;

(15) Methadone;

(16) Methadone-intermediate, 4-cyano-2-dimethylamino-4,4-diphenylbutane;

(17) Moramide-Intermediate, 2-methyl-3-morpholino-1,1-diphenyl-propane-carboxylic acid;

(18) Pethidine (Meperidine);

(19) Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine;

(20) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate;

(21) Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid;

(22) Phenazocine;

(23) Piminodine;

(24) Racemethorphan;

(25) Racemorphan;

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- (26) Remifentanil;
- (27) Sufentanil;
- (28) Tapentadol.

(c) Unless excepted or placed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a potential for abuse associated with a stimulant effect on the central nervous system:

- (1) Amphetamine, its salts, optical isomers, and salts of its optical isomers;
- (2) any substance which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers;
- (3) Methylphenidate;
- (4) Phenmetrazine and its salts;
- (5) Lisdexamfetamine and its salts, isomers and salts of isomers.

(d) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

- (1) Amobarbital;
 - (2) Glutethimide;
 - (3) Pentobarbital;
 - (4) Phencyclidine; and
 - (5) Secobarbital.
- (e) Hallucinogenic Substances:

- (1) Nabilone.

(f) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances:

- (1) Immediate precursor to Amphetamine and Methamphetamine; Phenylacetone (some trade names or other names); phenyl-2-propanone; P2P; benzyl methyl ketone; methyl benzyl ketone;
- (2) immediate precursors to phencyclidine (PCP);
 - (A) 1-phencylohexylamine;
 - (B) 1-piperidinocyclohexanecarbonitrile (PCC).

(g) Marijuana, including any material, compound, mixture or preparation which contains its salts, isomers and salts of isomers, unless specifically excepted, whenever the existence of these salts, isomers, and salts of isomers is possible within the specific chemical designation.

(Effective July 23, 1987; Amended August 22, 1995; Amended March 6, 2000; Amended June 10, 2003; Amended June 10, 2011; Amended September 17, 2013)

Sec. 21a-243-9. Controlled substances in schedule III

The controlled substances listed in this regulation are included by whatever official,

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common, usual, chemical, or trade name designation in Schedule III:

(a) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

- (1) Benzphetamine;
- (2) Chlorphentermine;
- (3) Clortermine;
- (4) Phendimetrazine.

(b) Unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a potential for abuse associated with a depressant effect on the central nervous system:

(1) Any compound, mixture or preparation containing: Amobarbital, Secobarbital, Pentobarbital or any salt thereof and one or more other active medicinal ingredients which are not listed in any schedule;

(2) Any suppository dosage form containing Amobarbital, Secobarbital, Pentobarbital or any salt of any of these drugs and approved by the Food and Drug Administration for marketing only as a suppository;

(3) Any substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid, except those substances which are specifically listed in other schedules, except that the following analgesic products shall not be considered to be controlled substances:

(A) Products containing a ratio of fifteen milligrams of long or intermediate acting barbiturates combined with at least one of the following:

- (i) 188 mg aspirin;
- (ii) 375 mg salicylamide; or
- (iii) 70 mg phenacetin, acetanilid or acetaminophen;

(B) Products containing a ratio of fifteen milligrams of short acting barbiturates combined with at least one of the following:

- (i) 307 mg aspirin;
- (ii) 614 mg salicylamide; or
- (iii) 106 mg phenacetin, acetanilid or acetaminophen;

(4) Any compound, mixture or preparation containing equal weights of both tiletamine and zolazepam or any salt thereof and not mixed with other psychoactive substances;

- (5) Chlorhexadol;
- (6) Embutramide;

(7) Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a United States Food and Drug Administration approved drug product;

- (8) Ketamine or any salt thereof;
- (9) Lysergic acid;

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- (10) Lysergic acid amide;
- (11) Methyprylon;
- (12) Sulfondiethylmethane;
- (13) Sulfonethylmethane;
- (14) Sulfonmethane.
- (c) Buprenorphine.
- (d) Nalorphine.
- (e) Any material, compound, mixture or preparation containing limited quantities of any of the following narcotic drugs or any salts thereof:
 - (1) Not more than 1.8 grams of codeine, or any of its salts, per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium;
 - (2) not more than 1.8 grams of codeine, or any of its salts, per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;
 - (3) not more than 300 milligrams of dihydrocodeinone, or any of its salts, per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium;
 - (4) not more than 300 milligrams of dihydrocodeinone, or any of its salts, per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;
 - (5) not more than 1.8 grams of dihydrocodeine, or any of its salts, per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;
 - (6) not more than 300 milligrams of ethylmorphine, or any of its salts, per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more ingredients in recognized therapeutic amounts;
 - (7) not more than 500 milligrams of opium per 100 milliliters or per 100 grams, or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;
 - (8) not more than 50 milligrams of morphine, or any of its salts, per 100 milliliters or per 100 grams with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
- (f) Unless expressly intended for administration through implants to nonhuman species and approved for such use by the Federal Food and Drug Administration, any anabolic steroid including but not limited to, any of the following, or any isomer, ester, salt or derivative of the following that acts in the same manner on the human body:
 - (1) 3[beta],17-dihydroxy-5a-androstane;
 - (2) 3[alpha],17[beta]-dihydroxy-5a-androstane;
 - (3) 5[alpha]-androstane-3,17-dione;
 - (4) 1-androstenediol (3[beta],17[beta]-dihydroxy-5[alpha]-androst-1-ene);

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- (5) 1-androstenediol (3[alpha],17[beta]-dihydroxy-5[alpha]-androst-1-ene);
- (6) 4-androstenediol (3[beta],17[beta]-dihydroxy-androst-4-ene);
- (7) 5-androstenediol (3[beta],17[beta]-dihydroxy-androst-5-ene);
- (8) 1-androstenedione ([5[alpha]]-androst-1-en-3,17-dione);
- (9) 4-androstenedione (androst-4-en-3,17-dione);
- (10) 5-androstenedione (androst-5-en-3,17-dione);
- (11) Boldenone;
- (12) Boldione;
- (13) Chlorotestosterone;
- (14) Clostebol;
- (15) Dehydrochlormethyltestosterone;
- (16) [Delta]1-dihydrotestosterone (a.k.a. '1-testosterone') (17[beta]- hydroxy-5[alpha]-androst-1-en-3-one);
- (17) desoxymethyltestosterone;
- (18) Dihydrotestosterone;
- (19) Drostanolone;
- (20) Ethylestrenol;
- (21) Fluoxymesterone;
- (22) Formebolone;
- (23) Furazabol (17[alpha]-methyl-17[beta]-hydroxyandrostano[2,3-c]- furazan);
- (24) 13[beta]-ethyl-17[beta]-hydroxygon-4-en-3-one;
- (25) 4-hydroxytestosterone (4,17[beta]-dihydroxy-androst-4-en-3-one);
- (26) 4-hydroxy-19-nortestosterone (4,17[beta]-dihydroxyestr-4-en-3- one);
- (27) Mestanolone (17[alpha]-methyl-17[beta]-hydroxy-5-androstan-3- one);
- (28) Mesterolone;
- (29) Methandienone;
- (30) Methandranone;
- (31) Methandriol;
- (32) Methandrostenolone;
- (33) Methenolone;
- (34) 17[alpha]-methyl-3[beta], 17[beta]-dihydroxy-5a-androstane;
- (35) 17[alpha]-methyl-3[alpha],17[beta]-dihydroxy-5a-androstane;
- (36) 17[alpha]-methyl-3[beta],17[beta]-dihydroxyandrost-4-ene;
- (37) 17[alpha]-methyl-4-hydroxynandrolone (17[alpha]-methyl-4-hydroxy-17[beta]-hydroxyestr-4-en-3-one);
- (38) Methyldienolone (17[alpha]-methyl-17[beta]-hydroxyestra-4,9(10)-dien-3-one);
- (39) Methyltrienolone (17[alpha]-methyl-17[beta]-hydroxyestra-4,9-11-trien-3-one);
- (40) Methyltestosterone;
- (41) Mibolerone;
- (42) 17[alpha]-methyl-[Delta]1-dihydrotestosterone (17b[beta]- hydroxy-17[alpha]-methyl-5[alpha]-androst-1-en-3-one) (a.k.a. '17- [alpha]-methyl-1-testosterone');

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- (43) Nandrolone;
- (44) 19-nor-4,9 (10)-androstadienedione;
- (45) 19-nor-4-androstenediol (3[beta], 17[beta]-dihydroxyestr-4-ene);
- (46) 19-nor-4-androstenediol (3[alpha], 17[beta]-dihydroxyestr-4-ene);
- (47) 19-nor-5-androstenediol (3[beta], 17[beta]-dihydroxyestr-5-ene);
- (48) 19-nor-5-androstenediol (3[alpha], 17[beta]-dihydroxyestr-5-ene);
- (49) 19-nor-4-androstenedione (estr-4-en-3,17-dione);
- (50) 19-nor-5-androstenedione (estr-5-en-3,17-dione);
- (51) Norbolethone (13[beta], 17[alpha]-diethyl-17[beta]-hydroxygon- 4-en-3-one);
- (52) Norclostebol (4-chloro-17[beta]-hydroxyestr-4-en-3-one);
- (53) Norethandrolone;
- (54) Norethandrolone (17[alpha]-ethyl-17[beta]-hydroxyestr-4-en-3- one);
- (55) Normethandrolone (17[alpha]-methyl-17[beta]-hydroxyestr-4-en-3-one);
- (56) Oxandrolone;
- (57) Oxymesterone;
- (58) Oxymetholone;
- (59) Stenbolone (17[beta]-hydroxy-2-methyl-[5[alpha]]-androst-1-en-3- one);
- (60) Stanolone;
- (61) Stanozolol;
- (62) Testolactone;
- (63) Testosterone;
- (64) Tetrahydrogestrinone (13[beta], 17[alpha]-diethyl-17[beta]- hydroxygon-4,9,11-trien-3-one);
- (65) Trenbolone.
- (g) Chorionic gonadotropin.
- (h) Any quantity of the following substances having a depressant effect on the central nervous system, including their salts, isomers and salts of such isomers, and esters:
 - (1) Gamma-hydroxy butyric acid if contained in a product for which an application has been approved under section 505 of the federal food, drug and cosmetic act; or
 - (2) Gamma-butyrolactone.

(Effective November 25, 1991; Amended March 6, 2000; Amended June 10, 2003; Amended June 10, 2011)

Sec. 21a-243-10. Controlled substances in schedule IV

The controlled substances listed in this regulation are included by whatever official, common, usual, chemical, or trade name designation in Schedule IV:

- (a) Any material, compound, mixture or preparation which contains any quantity of the following substances having a potential for abuse associated with a depressant effect on the central nervous system:
 - (1) Alprazolam;
 - (2) Barbital;

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- (3) Bromazepam;
- (4) Camazepam;
- (5) Carisoprodol;
- (6) Chloral betaine;
- (7) Chloral hydrate;
- (8) Chlordiazepoxide;
- (9) Clobazam;
- (10) Clonazepam;
- (11) Clorazepate;
- (12) Clotiazepam;
- (13) Cloxazolam;
- (14) Delorazepam;
- (15) Diazepam;
- (16) Dochloralphenazone;
- (17) Estazolam;
- (18) Etholorvynol;
- (19) Ethinamate;
- (20) Ethyl-lofiazepate;
- (21) Fludiazepam;
- (22) Flunitrazepam;
- (23) Flurazepam;
- (24) Halazepam;
- (25) Haloxazolam;
- (26) Ketazolam;
- (27) Loprazolam;
- (28) Lorazepam;
- (29) Lormetazepam;
- (30) Mebutamate;
- (31) Medazepam;
- (32) Meprobamate;
- (33) Methohexital;
- (34) Methylphenobarbital (mephobarbital);
- (35) Midazolam;
- (36) Nimetazepam;
- (37) Nitrazepam;
- (38) Nordiazepam;
- (39) Oxazepam;
- (40) Oxazolam;
- (41) Paraldehyde;
- (42) Petrichloral;
- (43) Phenobarbital;

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- (44) Pinazepam;
- (45) Prazepam;
- (46) Quazepam;
- (47) Temazepam;
- (48) Tetrazepam;
- (49) Triazolam;
- (50) Zaleplon;
- (51) Zolpidem;
- (52) Zopiclone.

(b) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

- (1) Cathine;
- (2) Diethylpropion;
- (3) Fencamfamin;
- (4) Fenproporex;
- (5) Mazindol;
- (6) Mefenorex;
- (7) Modafinil;
- (8) Pemoline
- (9) Phentermine
- (10) Pipradol;
- (11) Sibutramine;
- (12) SPA [(-)dimethylamino-1,2-diphenylethane].

(c) Any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

- (1) Fenfluramine.

(d) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or any salts thereof:

- (1) Not more than 1 milligram of Difenoxin and not less than 25 micrograms of Atropine Sulfate per dosage unit;
- (2) Dextropropoxyphene.

(e) Unless specifically exempted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances, including its salts:

- (1) Butorphanol; or

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(2) Pentazocine.

(Effective November 25, 1991; Amended August 22, 1995; Amended June 3, 1998; Amended December 4, 1998; Amended June 10, 2003; Amended June 10, 2011)

Sec. 21a-243-11. Controlled substances in schedule V

The controlled substances listed in this regulation are included by whatever official, common, usual, chemical, or trade name designation in Schedule V:

(a) Any compound, mixture, or preparation containing limited quantities of any of the following controlled drugs, which also contain one or more noncontrolled active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation, valuable medicinal qualities other than those possessed by the controlled drug alone:

(1) not more than 200 milligrams of codeine, or any of its salts, per 100 milliliters or per 100 grams;

(2) not more than 100 milligrams of dihydrocodeine, or any of its salts, per 100 milliliters or per 100 grams;

(3) not more than 100 milligrams of ethylmorphine, or any of its salts, per 100 milliliters or per 100 grams;

(4) not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit;

(5) not more than 100 milligrams of opium per 100 milliliters or per 100 grams;

(6) not more than 0.5 milligrams of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

(b) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of such isomers:

(1) Pyrovalerone

(Effective July 23, 1987; Amended August 22, 1995; Amended June 10, 2003)

Drug Prescriptions Transmitted by Facsimile Machines

Sec. 21a-243-12. Definitions

For the purpose of Sections 21a-243-12 through 21a-243-17 of the Regulations of Connecticut State Agencies, the following terms shall have the meanings indicated:

(a) “Controlled substance” has the meaning given to this term by Connecticut General Statutes, Section 21a-240(9);

(b) “Facsimile machine” means a machine that electronically transmits facsimiles through connection with a telephone network;

(c) “Prescribing Practitioner” means any person licensed by the state of Connecticut, any other state, the District of Columbia or the Commonwealth of Puerto Rico and authorized to prescribe controlled substances within the scope of his or her practice; and

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(d) “Long Term Care Facility” means a facility or institution as defined by the federal government in 21 CFR 1300.01.

(Effective October 1, 1991; Amended January 11, 1999)

Sec. 21a-243-13. Dispensing of prescriptions transmitted by means of a facsimile machine

No pharmacist or pharmacy may dispense controlled substances upon a prescription transmitted by means of a facsimile machine unless such prescription fully complies with Sections 21a-243-14 through 21a-243-18, inclusive, of the Regulations of Connecticut State Agencies.

(Effective October 1, 1991; Amended January 11, 1999)

Sec. 21a-243-14. Schedule II controlled substances

(a) Prescriptions for Schedule II controlled substances may be transmitted by a prescribing practitioner or his agent to a pharmacy by means of a facsimile machine provided the original written, signed prescription is provided to the pharmacist for review prior to the actual dispensing of the controlled substance, except as provided for in subsections (b) and (c) of this section. The original written prescription, once received by the pharmacist, shall be reviewed to ensure that it conforms with the requirements of section 21a-249 of the Connecticut General Statutes and shall be maintained as the original record of dispensing. The facsimile prescription order shall not be considered to be the actual prescription, but only a record of the transmission of the prescription order.

(b) Prescriptions for Schedule II narcotic substances to be compounded for direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may be transmitted by the prescribing practitioner or his agent to a pharmacy by facsimile. The prescription transmitted via facsimile will be accepted as the original prescription for purposes of this section.

(c) Prescriptions for Schedule II controlled substances for patients of a long term care facility may be transmitted by a prescribing practitioner or his agent to the dispensing pharmacy by facsimile. The prescription transmitted via facsimile will be accepted as the original prescription for purposes of this section.

(d) Prescriptions transmitted by facsimile machine in accordance with subsections (b) and (c) of this section shall comply with the requirements set forth in subsection (b) of Section 21a-243-15 of the Regulations of Connecticut State Agencies.

(Effective October 1, 1991; Amended October 3, 1995; Amended January 11, 1999)

Sec. 21a-243-15. Schedule III, IV and V controlled substances

(a) Prescriptions for Schedule III, IV and V controlled substances may be transmitted by a prescribing practitioner or his agent to a pharmacy by means of a facsimile machine.

(b) All prescriptions transmitted pursuant to subsection (a) of this section must comply with the following in addition to any other requirement of federal or state statute or

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regulation:

(1) The facsimile prescription shall clearly contain the name of the pharmacy to which the facsimile is being transmitted and the name of the facility from which it is transmitted if the prescription is written for an inpatient of a chronic or convalescent nursing home or a rest home with nursing supervision;

(2) The facsimile prescription shall clearly display a statement in substantially the following form: “This prescription is valid only if transmitted by means of a facsimile machine”; and

(3) The facsimile document may be maintained as the actual prescription only if the nature of the equipment and paper ensures that the prescription will remain non-fading and durable for the minimum amount of time required for the maintenance of prescription records under federal and state statute or regulation. If the document will not remain non-fading or durable, the prescription transmitted by facsimile machine shall be reduced to writing, photocopied or converted to an individual printout.

(Effective October 1, 1991; Amended October 3, 1995; Amended January 11, 1999)

Sec. 21a-243-16. Accuracy of prescription

If a pharmacist questions the accuracy or authenticity of a prescription transmitted by facsimile machine, he or she shall contact the prescribing practitioner for verification before dispensing the prescription.

(Effective October 1, 1991; Amended October 3, 1995)

Sec. 21a-243-17. Relationship with prescribing practitioners and health care facilities

(a) No pharmacist or pharmacy shall maintain direct telephone, facsimile machine or computer lines to any health care facility or prescribing practitioner’s office.

(b) No pharmacist shall enter into any agreement with a prescribing practitioner or health care facility concerning the provision of facsimile machine services or equipment which adversely affects any person’s freedom to choose the pharmacy at which a prescription will be filled.

(Effective October 1, 1991; Amended January 11, 1999)

Sec. 21a-243-18. Control of prescription forms

It shall be the responsibility of the prescribing practitioner to ensure that the prescription form that is used to transmit a prescription by facsimile machine is either destroyed immediately or marked or controlled in such a manner that prevents the use of such form to obtain controlled substances other than as authorized by these regulations.

(Adopted effective October 3, 1995)

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Storage and Retrieval of Prescription Information for Controlled Substances

Sec. 21a-244-1. Computer systems requirements

(a) All prescriptions for schedule II controlled substances, and original written and oral prescriptions for schedule III, IV and V controlled substances shall be received, executed and filed in accordance with sections 21a-249 and 21a-250 of the Connecticut General Statutes and all applicable federal laws and regulations. In the case of original oral prescriptions for schedule III, IV and V controlled substances, which shall be received by a pharmacist, an individual hard copy printout of the prescription containing all required information may be used to satisfy the requirements of section 21a-249 (d) of the Connecticut General Statutes.

(b) In the case of refills of prescriptions for schedule III, IV and V controlled substances, an automated data processing system may be used for the storage and retrieval of refill information. Any such computerized system shall provide on-line retrieval for a period of at least six months from the date of the last recorded dispensing via visual display device or hardcopy printout of original prescription order information for all prescriptions including those prescription orders which are currently authorized for refilling. This shall include but is not limited to data such as:

- (1) the original prescription number;
- (2) the date of issuance of the original prescription order by the prescribing practitioner;
- (3) the full name and complete address of the patient;
- (4) the full name, full address, and Drug Enforcement Administration, United States Department of Justice, or its successor agency registration number of the prescribing practitioner;
- (5) the name, strength, dosage form, quantity of the controlled substance prescribed and quantity dispensed if different from the quantity prescribed; and
- (6) the total number of refills authorized by the prescribing practitioner.

(Effective July 27, 1984; Amended January 11, 1999)

Sec. 21a-244-2. Refill history capability requirement

Any computerized system must also provide on line retrieval via visual display device or hard copy printout of the current refill history for Schedule III, IV, or V controlled substance prescription orders which are currently authorized for refilling. This refill history shall include but is not limited to:

- (a) the full name and address of patient;
- (b) the full name and complete address of the prescribing practitioner;
- (c) the name, strength and dosage form of the controlled substance;
- (d) the date of refill;
- (e) the quantity dispensed;
- (f) the date on which the prescription was first dispensed;
- (g) the original number assigned to said prescription;
- (h) the name or initials of the dispensing pharmacist for each refill; and

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- (i) the total number of refills dispensed to date for that prescription order.

(Effective July 27, 1984; Amended January 11, 1999)

Sec. 21a-244-3. Documentation of data requirement

Documentation of the fact that the refill information entered into the computer each time a pharmacist refills an original prescription order for a Schedule III, IV or V controlled substance is correct must be provided by the individual pharmacist who makes use of such a system. In order to accomplish this documentation, a pharmacy using such a computerized system must provide either:

(1) a separate hard-copy printout of controlled substance prescription order refill data for each day. This hard copy printout shall include the refill data mentioned in section 21a-244-2 of the Regulations of Connecticut State Agencies except that it need not contain the address of the patient or the address of the prescribing practitioner. Each prescription on said printout shall be reviewed by each individual pharmacist who refilled such a prescription order. The individual pharmacist must verify that the data indicated is correct and then sign this document in the same manner as he would sign a check or legal document. This document shall be maintained in a separate file at that pharmacy for a period of three years from the dispensing date. This printout of the controlled substance prescription order refill data must be provided by each pharmacy using such a computerized system within 72 hours of the date on which the refill was dispensed and must be verified and signed by each pharmacist who effected such dispensing as soon as possible after receipt. In no case shall the printout be verified and signed later than the pharmacist's first work period following receipt of the document; or

(2) In lieu of producing a hardcopy printout of daily refill information signed by each dispensing pharmacist, the pharmacy shall maintain a bound log book or separate file which each pharmacist involved in such dispensing shall sign in the same manner as he would sign a check or legal document. The signature of the dispensing pharmacist shall indicate that he has reviewed the refill information entered into the computer, which is attributed to him, for each date of dispensing and that it is correct as shown. Whenever possible, this log book or separate file shall be signed by each pharmacist on the date of dispensing but in no case shall it be signed later than the pharmacist's first work period in that pharmacy after such date.

(Effective July 27, 1984; Amended January 11, 1999)

Sec. 21a-244-4. Information available to commissioner upon request

Any computerized system shall have the capability of producing a printout of any refill data which the utilizing pharmacy is responsible for maintaining under Chapter 420b of the general statutes and the regulations promulgated thereunder. This shall include the capability to produce a refill by refill audit trail for any specified strength and dosage form of any controlled substance by either brand or generic name or both. Said printout shall be produced within 48 hours and shall indicate the following:

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- (a) the name of the prescribing practitioner;
- (b) the name and address of the patient;
- (c) the name, dosage form, strength, and quantity of the drug dispensed on each refill;
- (d) the name or initials of the dispensing pharmacist and the date of dispensing for each refill; and
- (f) the number of the original prescription order.

Any pharmacy utilizing a computerized system and authorized to maintain records at a central record-keeping location, must be capable of obtaining the requested printout within 48 hours.

(Effective July 27, 1984; Amended January 11, 1999)

Sec. 21a-244-5. Auxiliary system provision

In the event that a pharmacy which employs such a computerized system experiences system down-time, the pharmacy must have an auxiliary procedure which will be used for documentation of refills of Schedule III, IV or V controlled substance prescription orders. This auxiliary procedure must insure that refills are authorized by the original prescription order and that all of the appropriate data is retained for on-line data entry as soon as the computer system is available for use again. All prescriptions refilled during the down-time shall be confirmed as being authorized upon resumption of on-line service.

(Effective July 27, 1984)

Sec. 21a-244-6. When handwritten system is allowed

If an automated data processing system is used for the storage and retrieval or refill information for prescription orders as authorized by Section 21a-244 of the general statutes, and the regulations promulgated thereunder, the pharmacy may use a traditional, handwritten system only to satisfy the requirement of Section 21a-244-5 of the regulations of State agencies.

(Effective July 27, 1984)

Sec. 21a-244-7. Notice to commissioner upon commencement of use

Any pharmacy instituting an automated data processing system for the storage and retrieval of refill information for prescription orders as authorized by Section 21a-244 of the general statutes and the regulations promulgated thereunder shall notify in writing the Drug Control Division of the Department of Consumer Protection at least 30 days prior to the commencement of usage of said system.

(Effective July 27, 1984)

Sec. 21a-244-8. Compliance with federal law

Notwithstanding the provisions of Section 21a-244 of the general statutes and the regulations promulgated thereunder, there must be compliance with all applicable federal

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laws.

(Effective July 27, 1984)

Sec. 21a-244-9. Requirement of safeguards

If an automated data processing system is used for the storage and retrieval of refill information for prescription orders as authorized by Section 21a-244 of the general statutes and the regulations promulgated thereunder, it shall:

- (a) guarantee the confidentiality of the information contained in the data bank; and
- (b) be capable of providing safeguards against erasures and unauthorized changes in data after the information has been entered and verified by the pharmacist.

(Effective July 27, 1984)

Sec. 21a-244-10. Reconstruction of data in case of accident

If an automated data processing system is used for the storage and retrieval of refill information for prescription orders as authorized by Section 21a-244 of the general statutes and the regulations promulgated thereunder, said automated data processing system shall be capable of being reconstructed in the event of a computer malfunction or accident resulting in the destruction of the data bank.

(Effective July 27, 1984)

Sec. 21a-244-11. Discontinuance of data processing system

In the event that a pharmacy using an electronic data processing system for storage and retrieval of information goes out of business, sells out to another pharmacy that does not wish to use such a system, or discontinues use of the computer system, the pharmacy shall:

- (a) notify the Drug Control Division of the Department of Consumer Protection in writing at least 30 days prior to discontinuance of said system;
- (b) provide an up-date hard-copy printout of all prescriptions stored in the automated system for the three years immediately preceding as part of the final records of that pharmacy prior to a change over to a manual system; and
- (c) make provision for these records to be available to any nearby pharmacy in the event that the pharmacy closes, as provided in Section 20-615 of the general statutes.

(Effective July 27, 1984; Amended January 11, 1999)

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Electronic Drug Records Maintained by Hospital and Medical Practitioners

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Electronic Drug Records Maintained by Hospital and Medical Practitioners

Sec. 21a-244a-1.

As used in section 21a-244a-2 to section 21a-244a-4, inclusive, of the Regulations of Connecticut State Agencies:

(1) “Drug record” means “drug record” as defined in section 21a-244a of the Connecticut General Statutes;

(2) “Hospital” means “hospital” as defined in section 19a-490 of the Connecticut General Statutes; and

(3) “Licensed practitioner” means “licensed practitioner” as defined in section 21a-244a of the Connecticut General Statutes.

(Adopted effective September 7, 1999; Amended April 13, 2015)

Sec. 21a-244a-2.

Hospitals and licensed practitioners may create and maintain drug records using an electronic data processing system, provided they comply with the requirements of sections 21a-244a-3 and 21a-244a-4 of the Regulations of Connecticut State Agencies.

(Adopted effective September 7, 1999; Amended April 13, 2015)

Sec. 21a-244a-3.

Hospitals and licensed practitioners shall establish and comply with a policy in creating and maintaining electronic drug records. This policy shall be maintained electronically or in writing, shall be dated and shall accurately reflect the manner in which electronic drug records are currently created and maintained. This policy shall be readily available for inspection by the Department of Consumer Protection for a period of three years from its last effective date.

(Adopted effective September 7, 1999; Amended April 13, 2015)

Sec. 21a-244a-4.

Any hospital or licensed practitioner, in establishing the policy required by section 21a-244a-3 of the Regulations of Connecticut State Agencies, shall include:

(1) a description of the electronic data processing system being used to create and maintain records. This description shall include at least the following information:

(A) the specific types of drug records being maintained electronically on the system; and

(B) the patient populations and physical locations for which the electronic drug record system is being utilized;

(2) the specific types of electronic identifiers, including but not limited to those listed in section 21a-244a(c) of the Connecticut General Statutes, that are utilized to access the electronic system, or used in place of written signatures or initials where required. All electronic identifiers described in the system shall be unique to an individual and shall be controlled in a secure manner;

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(3) the manner in which access to the electronic drug record system is controlled. This shall, at a minimum, include:

(A) a description of the general levels of access into the system; and

(B) the mechanism used to identify all individuals having access to the electronic system, their level of access and a description of how this access data is maintained by the hospital or the licensed practitioner;

(4) the method by which individual electronic identifiers allowing access to the system are issued, maintained and terminated. This shall include, at a minimum, the following information:

(A) the specific individual or group responsible for issuing, maintaining or terminating electronic identifiers;

(B) the procedure by which electronic identifiers are issued, maintained and terminated; and

(C) the method by which the uniqueness of electronic identifiers is established and their security maintained;

(5) the system by which electronic drug records are stored on-line, archived or maintained in some other manner that ensures that they are readily retrievable for a period of not less than three years;

(6) the recovery procedure utilized to reconstruct electronic drug records in the event the system experiences unscheduled downtime;

(7) the procedure utilized to routinely backup data stored on the electronic system to prevent the loss or destruction of electronic drug records;

(8) the method employed to prevent or detect unauthorized alteration or erasure of electronic drug records maintained on the system; and

(9) the procedure employed to ensure that all information contained in electronic drug records that is deemed to be confidential is appropriately protected from unauthorized access and dissemination. Such confidential information shall, at a minimum, include the names of patients and prescribing practitioners. The electronic data processing system shall comply with all federal and state statutes and regulations pertaining to the confidentiality of patient drug records.

(Adopted effective September 7, 1999; Amended April 13, 2015)

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Record Keeping for Controlled Drugs

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Record Keeping for Controlled Drugs

Sec. 21a-254-1. Records

(a) In general, special and long-term hospitals there shall be a separate proof of use sheet as required in subsection (e) of section 21a-254 of the general statutes for controlled drugs which are not dispensed or administered directly to patients from the hospital's pharmacy but are administered or dispensed from each floor stock. Such proof of use record shall show the date of administering or dispensing, the name of the person to whom or for whose use the drug is administered or dispensed, the kind and quantity of drug, the time of administering or dispensing, the prescribing physician and the nurse administering or dispensing the drug.

(b) In general, special and long-term hospitals where controlled drugs are dispensed or administered directly to patients from the hospital's pharmacy in quantities not exceeding four days' supply, the hospital may use a duplicate copy of the patient's medication record to record the drug administration or dispensing in lieu of a separate proof of use record as required by said subsection (e) of section 21a-254. Such records and any unused drugs or portions thereof shall be promptly returned to the hospital pharmacy when no longer required by the patient.

(Effective July 27, 1984)

Electronic Prescription Drug Monitoring Program

Sec. 21a-254-2. Definitions

As used in sections 21a-254-2 to 21a-254-7, inclusive, of the Regulations of Connecticut State Agencies:

(1) "Controlled substance" means "controlled substance" as defined in section 21a-240 of the Connecticut General Statutes;

(2) "Department" means the Department of Consumer Protection;

(3) "Pharmacy" means "pharmacy" as defined in section 20-571 of the Connecticut General Statutes, or a pharmacy located in a hospital, long term care facility or correctional facility; and

(4) "Practitioner" means "Prescribing practitioner" as defined in section 20-571 of the Connecticut General Statutes.

(Adopted effective August 1, 2007)

Sec. 21a-254-3. General requirements

A pharmacy that dispenses schedule II, III, IV, and V controlled substances shall transmit the prescription information for these controlled substances to the department. A hospital pharmacy, long term care facility pharmacy or correctional facility pharmacy shall transmit controlled prescription information for outpatients only.

(Adopted effective August 1, 2007)

Sec. 21a-254-4. Reporting

(a) A pharmacy that maintains prescription information electronically, and that dispenses a schedule II, III, IV, or V controlled substance to a person who is not an inpatient of a hospital, correctional institution or nursing facility, shall transmit electronically to the Drug Control Division of the department the information set forth in the most recent edition of the Electronic Reporting Standard for Prescription Monitoring Programs established by the American Society for Automation in Pharmacy. A pharmacy shall transmit to the department the fields listed in said reporting standard, including, but not limited to, the following:

- (1) Drug Enforcement Administration Pharmacy number;
- (2) Birth date;
- (3) Sex code;
- (4) Date prescription filled;
- (5) Prescription number;
- (6) New-refill code;
- (7) Quantity;
- (8) Days supply;
- (9) National Drug Code number;
- (10) Drug Enforcement Administration Prescriber identification number;
- (11) Date prescription written;
- (12) Number of refills authorized;
- (13) Prescription origin code;
- (14) Patient last name;
- (15) Patient first name;
- (16) Patient street address;
- (17) State;
- (18) Payment code for either cash or third-party provider; and
- (19) Drug name.

(b) A copy of the Electronic Reporting Standard for Prescription Monitoring Programs may be obtained from the American Society for Automation in Pharmacy, 492 Norristown Road, Suite 160, Blue Bell, Pennsylvania 19422. Telephone: (610) 825-7783. Website: www.asapnet.org.

(c) A pharmacy that maintains prescription information electronically shall transmit the required information by means of one of the following methods:

- (1) Electronic data transmission through a computer modem that can transmit information at a rate of 2400 baud or more;
- (2) Computer disc; or
- (3) Magnetic tape of the kind that is used to transmit information between computerized systems.

(d) A pharmacy that does not maintain prescription information electronically, and that dispenses a schedule II, III, IV, or V controlled substance to a person who is not an inpatient of a hospital, correctional institution or nursing facility, shall transmit to the Drug Control

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Division of the department the information set forth in subsection (a) of this section on a paper form provided by the department.

(e) (1) A pharmacy shall transmit to the department the information required pursuant to this section not later than:

(A) The 20th day of the month for all prescriptions dispensed on and between the 1st and the 15th days of the month; and

(B) The 5th day of the following month for all prescriptions dispensed on and between the 16th day and the last day of the month.

(2) If the reporting date falls on weekend or a holiday, a pharmacy shall transmit the required information by the next state of Connecticut workday.

(f) A pharmacy shall transmit the information required pursuant to this section in such a manner as to insure the confidentiality of the information in compliance with all federal and state statutes and regulations, including the federal Health Insurance Portability and Accountability Act of 1996.

(Adopted effective August 1, 2007)

Sec. 21a-254-5. Evaluation

Agents of the Drug Control Division of the department, and any department employee authorized to work with the Drug Control Division, shall evaluate the controlled substance prescription information received from pharmacies. The department shall evaluate the prescription information for the purposes of preventing controlled substance diversion, public health initiatives, and statistical reporting.

(Adopted effective August 1, 2007)

Sec. 21a-254-6. Management of information

The department may provide prescription information obtained from pharmacies to:

(a) Other regulatory, investigative or law enforcement agencies for disciplinary, civil, or criminal purposes;

(b) Practitioners, for the purpose of education in lieu of disciplinary, civil or criminal action;

(c) Practitioners and pharmacists, for the purposes of patient care, drug therapy management and monitoring of controlled substances obtained by the patient; and

(d) Public or private entities, for statistical, research, or educational purposes, provided that the privacy of patients and confidentiality of patient information is not compromised.

(Adopted effective August 1, 2007)

Sec. 21a-254-7. Storage of information

(a) The department shall ensure the privacy of patients and confidentiality of patient information transmitted or obtained pursuant to sections 21a-254-2 to 21a-254-6, inclusive, of the Regulations of Connecticut State Agencies, and shall ensure that the patient information collected, recorded, transmitted, and stored is maintained in accordance with

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applicable state and federal laws, rules and regulations.

(b) The department shall retain the prescription information collected pursuant to sections 21a-254-2 to 21a-254-6, inclusive, of the Regulations of Connecticut State Agencies, for a minimum of three years.

(Adopted effective August 1, 2007)

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Subject

Minimum Security and Safeguard Requirements for Storage and Handling of Controlled Substances

Inclusive Sections

§§ 21a-262-1—21a-262-10

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Sec. 21a-262-9.	Hospital patient care areas, hospital nursing stations, other hospital drug storage locations, chronic and convalescent nursing homes, rest homes with nursing supervision, children's nursing homes, and areas and locations within correctiona
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Minimum Security and Safeguard Requirements for Storage and Handling of Controlled Substances

Sec. 21a-262-1. Definitions

(a) Controlled Substances means a drug, substance, or immediate precursor so designated as a controlled drug or controlled substance pursuant to state and/or federal drug laws and regulations.

(b) **Schedules of Controlled Substances.** For security purposes, each particular controlled substance shall be considered to be in the schedule as designated in each particular instance by applicable state and/or federal drug laws or regulations. In instances of conflict between state and federal drug laws or regulations, the controlled substances shall be considered to be in the schedule providing the highest degree of control.

(c) Registrant means any person of firm registered with the federal government for conduct of any business activity with controlled substances. The person signing the federal application for registration for controlled substances shall be considered to be the registrant for security purposes.

(d) **Classification of Registrants.** For security purposes, registrants shall be classified according to the business activity for which they are registered under the federal controlled substances act.

(e) **Controlled Substance(s) Units:** A controlled substance unit shall be a unit consisting of a quantity of controlled substance(s) which shall be determined according to the following formula:

#100 Tablets or Capsules—shall be 1 unit

One pint of a liquid—shall be 1 unit

1/8 ounce of a powder, crystal, flake, or granule—shall be 1 unit

One multiple dose vial—shall be 1 unit

Ten suppositories—shall be 1 unit

Ten single dose Ampules, Tubexes, Dosettes, Hyporettes, or other single dose package forms for injection whether powder or in solution—shall be 1 unit

The quantity of controlled substance(s) stocked by any registrant shall be determined for security purposes by totaling the number of controlled substance(s) units currently on hand. Partial containers of controlled substances shall be considered as being full when determining the total quantity of controlled substance stock. Larger package sizes shall be counted according to the number of controlled substance units they contain. Package sizes less than a full controlled substance unit shall be counted as the fraction of a controlled substance unit which the package size contains, i.e., #50 Tablets shall be counted as .5 controlled substance units.

(f) An approved safe or safe(s) as used in sections 21a-262-1 to 21a-262-10, inclusive, of the Regulations of Connecticut State Agencies means any safe(s) that has been approved prior to January 1, 1975 or any safe(s) which conforms to or exceeds all of the following standards:

(1) A minimum of a B Burglary Rate;

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- (2) Equipped with a relocking device;
- (3) Weight of 750 pounds or more or rendered immobile by being securely anchored to a permanent structure of the building; and
- (4) Adequate interior space to store all controlled substances required to be kept within the safe.

(g) An approved vault as used in sections 21a-262-1 to 21a-262-4 inclusive, means a vault approved prior to January 1, 1975 or a vault constructed after January 1, 1975 and meeting the following specifications or equivalent:

(1) Walls, floors, and ceilings constructed of at least 8 inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with 1/2 inch steel rods tied 6 inches on center, or the structural equivalent to such reinforced walls, floors, and ceilings.

(2) The door of the vault must contain a multiple-position combination lock or the equivalent, a relocking device or equivalent and steel plate with a thickness of at least 1/2 inch. (The GSA Class 5 rated steel door meets all the qualifications for the vault door.)

(3) The vault, if operations require it to remain open for frequent access, must be equipped with a “day gate” which is self-closing and self-locking or the equivalent. If the operation requires only that the vault be opened infrequently, such as to remove raw material in the morning and return raw material at night, and is always relocked immediately after use, a “day gate” is not required.

(4) The walls, floor, and ceiling of the vault must be equipped with an alarm which, when unauthorized entry is attempted, transmits a signal directly to a central station protection company, or a local or state police agency which has a legal responsibility to respond, or a 24-hour control station operated by the registrant. If necessary, due to local conditions or other problems, holdup buttons shall be placed at strategic points of entry to the perimeter area of the vault.

(5) The vault door must be equipped with a contact switch.

(6) The vault must have at least one of the following:

- a. Complete electrical lacing of the walls, floor and ceiling or
- b. Sensitive ultrasonic equipment within the vault or
- c. A sensitive sound accumulator system or
- d. Such other device designed to detect illegal entry as may be approved by the Commissioner of Consumer Protection.

(7) The electrical alarm system must be certified as being an Underwriters Laboratories, Inc., approved system and installation.

(Effective July 27, 1984; Amended April 3, 2007; Amended June 11, 2011)

Sec. 21a-262-2. Security requirements

(a) Requirements for minimum security and safeguard standards for storage and handling of controlled substances may be determined for each registrant by the Commissioner of Consumer Protection after consideration of the protection offered from an overall standpoint

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in instances wherein other security measures provided exceed those specifically stated. If the registrant has provided other safeguards which can be regarded in toto as an adequate substitute for some element of protection required of such registrant such as supervised watchman service, full electrical protection of the building, electric alarms, etc., such added protection may be taken into account in evaluating overall required security measures. In cases where special hazards exist such as extremely large stock, exposed handling, unusual vulnerability to loss, theft, diversion, or robbery, additional safeguards will be required by the Commissioner of Consumer Protection which may include approved vault(s), approved safe(s), electrical alarm protection, and/or hold up button(s).

(b) In all instances, registrants shall maintain all stocks of controlled substances in all schedules in a secure area or location accessible only to specifically authorized personnel. Such specific authorization should be given by registrants only to the minimum number of employees absolutely essential for efficient operation. All controlled substances should be stored in such a manner as to prevent theft or diversion of these preparations.

(c) In all instances, registrants shall maintain all equipment used for storage of controlled substances such as approved vault(s), approved safe(s), caged areas, cabinets, enclosures, etc., securely locked except for the actual time required to remove or replace needed items. Locks shall be kept in good working order with keys removed therefrom. Keys to the locks shall not be left in a location accessible to other than specifically authorized personnel.

(d) Any controlled substance(s) stored at any location not stored in compliance with section 21a-262-1 through section 21a-262-10 inclusive, or at a location other than that for which the person, firm, or business activity is registered under the Federal Controlled Substances Act shall be subject to seizure by the Commissioner of Consumer Protection. This action of seizure shall be considered as being in the best interests of the general public and said Commissioner shall not be held liable for any loss of revenues suffered by the person surrendering the drugs.

(e) Any wholesaler, manufacturer, or laboratory licensed by the Commissioner of Consumer Protection, who after due process, has his license revoked or suspended by said Commissioner, or who does not within 30 days apply for relicensure shall upon loss of said license dispose of his entire stock of controlled substances under conditions approved by the Commissioner or surrender his entire supply of controlled substances to said Commissioner. Any Licensed Pharmacy or any Practitioner who has his license revoked or suspended by his respective Licensing Board or who does not apply for relicensure, shall dispose of his entire stock of Controlled Substances under conditions approved by the Commissioner of Consumer Protection or shall surrender his entire stock of Controlled Substances to said Commissioner. This action of surrender shall be considered as being in the best interest of the general public, and said Commissioner shall not be held liable in any way for any loss of revenue suffered by the person surrendering these drugs.

(f) If any case where a loss, theft, burglary, or diversion of controlled substances has occurred, the Commissioner of Consumer Protection may require additional security safeguards which may include storage of any controlled substance(s) in an approved vault,

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approved safe, separate locked caged area, locked room or enclosure, or a substantially constructed locked steel or wood cabinet, or under effective electrical protection within 90 days of any such occurrence. In the case of hospitals, 180 days shall be allowed for this purpose.

(g) Registrants shall not maintain any stock of controlled substance(s) in excess of the quantity actually required for normal, efficient operation.

(Effective July 27, 1984)

Sec. 21a-262-3. Disposition of drugs

(a) Disposal of undesired, excess, unauthorized, obsolete, or deteriorated controlled substances shall be made by a registrant, person having title to, enforcement or court official, executor of an estate, or any other person in the following manner:

(1) By transfer to a person or firm registered under the Federal Controlled Substances Act and authorized to possess such controlled substances providing all state and federal required procedures are complied with.

(2) By following procedures as outlined in Sections 307.21 of the Code of Federal Regulations.

(3) By the following manner in the case of hospital pharmacies where small quantities of less than No. 10 controlled substance units are involved on any separate occasion:

(a) By destruction in such a manner as to render the controlled substance(s) nonrecoverable.

(b) By destruction conducted by a Connecticut licensed pharmacist in the presence of another Connecticut licensed pharmacist acting as a witness.

(c) By maintaining a separate record of each such destruction indicating the date, time, manner of destruction, the type, strength, form, and quantity of controlled substance(s) destroyed, and the signatures of the pharmacist destroying the controlled substance(s) and the pharmacist witness.

(4) By a manner rendering the controlled substance(s) nonrecoverable in cases where such controlled substance(s) are legally possessed by a person for his/her own personal use pursuant to a bonafide medical condition.

(5) By surrender without compensation of such controlled substance(s) to the Commissioner of Consumer Protection in all other instances.

(b) Reporting of loss, theft, or unauthorized destruction of controlled substances. Any loss, theft, or unauthorized destruction of any controlled substance(s) must be reported by a registrant within 72 hours of discovery of any such occurrence to the Commissioner of Consumer Protection as follows:

(1) Where through breakage of the container or other accident, otherwise than in transit, controlled substance(s) are lost or destroyed, the registrant shall make a signed statement as to the kinds and quantities of controlled substance(s) lost or destroyed and the circumstances involved. The statement shall be forwarded to the Commissioner of Consumer Protection and a copy retained by the registrant.

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(2) Where controlled substance(s) are lost by theft or otherwise lost or destroyed in transit, the consignee, and the consignor if within this state, shall forward to the Commissioner of Consumer Protection a signed statement which details the facts, includes an accurate listing of the controlled substance(s) stolen, lost, or destroyed and specifies that the local authorities were notified. A copy of the statement shall be retained by the registrant.

(Effective July 27, 1984)

Sec. 21a-262-4. Manufacturers, wholesalers, distributors, importers, and exporters

(a) Schedule II Stock if less than No. 250 controlled substance units shall be stored in an approved safe. If No. 250 or more controlled substance units all schedule II controlled substances shall be stored in an approved vault.

(b) Schedule III, IV, V Stock shall be stored in an approved vault, approved safe equipped with a separate effective electrical alarm system, or separate secure locked caged area, room, or enclosure equipped with a separate effective electrical alarm system. If a caged area or enclosure is used, such caged area or enclosure must be completely enclosed. If a caged area is used, construction must be of heavy gauge wire mesh having openings smaller than the smallest controlled substance(s) containers stocked.

(c) All controlled substances in the process of manufacture, distribution, transfer, or analysis shall be stored in such a manner as to prevent diversion; shall be accessible only to the minimum number of specifically authorized personnel essential for efficient operation; and shall be returned to the required security location immediately after completion of the procedure or at the end of the scheduled business day. If a manufacturing process cannot be completed at the end of a working day, the processing area or tanks, vessels, bins, or bulk containers containing controlled substances must be securely locked inside an area or building which affords adequate security.

(Effective July 27, 1984)

Sec. 21a-262-5. Licensed pharmacies

(a) Schedule II Stock, if less than No. 150 controlled substance units a substantially constructed completely enclosed locked wood or metal cabinet shall be used for storage of all schedule II controlled substance stock. If No. 150 or more controlled substance units an approved safe shall be used for storage of all schedule II controlled substance stock. Pharmacies newly licensed and/or relocating after Jan. 1, 1975 shall be required to store all schedule II controlled substances in an approved safe.

(b) Schedule III, IV, V Stock shall be stored in an approved safe, substantially constructed locked metal or wood cabinet, or dispersed throughout stock within the pharmacy prescription compounding area providing requirements of Section 21a-262-2 (b) are complied with and a loss, theft, or diversion of any controlled substance in any schedule has not occurred.

(c) In every case where loss, theft, burglary, or diversion of any controlled substance in any schedule has occurred from a licensed pharmacy, the Commissioner of Consumer

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Protection shall determine the appropriate storage and security requirements for all controlled substances in such pharmacy, and shall require additional safeguards to ensure the security of the controlled substances.

(d) The Commissioner of Consumer Protection may require any licensed pharmacy(ies) to store any controlled substance stock in an approved safe, or locked substantially constructed cabinet for security purposes when overall conditions warrant additional safeguards.

(Effective July 27, 1984; Amended June 10, 2011)

Sec. 21a-262-6. Practitioners including but not limited to medical doctors, dentists, veterinarians, osteopaths, and podiatrists

(a) Schedule II and III Controlled Substance Stock, if total is No. 15 controlled substance units or less shall be stored in a locked substantially constructed steel or wood cabinet in a securely safeguarded location. If the total quantity of schedule II and III controlled substance stock is more than 15 controlled substance units, such stock shall be stored in an approved safe. In the case of veterinary practitioners an additional No. 25 controlled substance units of schedule II or III controlled substance stock of the barbiturate-type, for use solely for animal anesthesia or animal euthenasia, may be stored in a locked substantially constructed steel or wood cabinet.

(b) Schedule IV and V Controlled Substance Stock shall be stored in a locked substantially constructed steel or wood cabinet or in a securely safeguarded location.

(c) In no case shall a practitioner's controlled substance stock be left unsecured or unattended in an examining room, treatment room, automobile, or in any other location assessable to nonauthorized persons.

(Effective July 27, 1984)

Sec. 21a-262-7. Laboratories other than hospital clinical laboratories

(a) Schedule I and II Controlled Substance Stock shall be stored in an approved safe except where schedule II stock of the barbiturate type is used solely for its sedative or anesthetic effect on animals and not more than No. 10 Controlled Substance units are stocked, in which cases security as outlined for schedule III controlled substances in Section 21a-262-7 (b) will apply. In instances in laboratories where schedule I or II stock may be unstable, of extremely small quantity, or of such a nature as to require special storage conditions, the Commissioner of Consumer Protection may approve of other security safeguards on an individual basis in lieu of those required by section 21a-262-1 through 21a-262-10 inclusive.

(b) Schedule III, IV or V Controlled Substances Stock shall be stored separately from other drugs and substances in an approved safe or separate secure locked location accessible only to the minimum number of specifically authorized personnel essential for efficient operation.

(c) Controlled Substances in the process of testing, use, or research shall be immediately

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returned to the required storage location upon completion of each such process.

(Effective July 27, 1984)

Sec. 21a-262-8. Pharmacies or other areas wherein controlled substances are stored, prepared, or dispensed exclusive of those specifically referred to in section 21a-262-9 and section 21a-262-10 located within licensed hospitals, mental health hospitals, mental retardation facilities, training schools, correctional institutions, juvenile training or youth services facilities, educational institutions, health maintenance organizations, health facilities, and within other care giving institutions or establishments including those which are private, state, or municipally operated, and including hospital drug rooms, hospital satellite pharmacies, and hospital clinical laboratories

(a) Schedule II and III Controlled Substance Stock in quantities of less than No. 150 controlled substance units shall be stored separately from other drugs and substances in a separate secure substantially constructed locked metal or wood cabinet. In the case of Hospital Clinical Laboratories, Schedule II Controlled Substance stock shall be stored in an approved safe.

Schedule II and III controlled substance stock in quantities of No. 150 controlled substance units or more but less than No. 1000 controlled substance units shall be stored in an approved safe.

Schedule II and III controlled substance stock in quantities of No. 1000 controlled substance units or more shall be stored in a completely enclosed masonry room or equivalent equipped with a vault-type steel door with horizontal or vertical locking bolts, having a three-tumbler combination lock and a relocking device. The completely enclosed masonry room or equivalent, if operations require it to be opened for frequent access, must be equipped with a "day gate" which is self-closing and self-locking or the vault type steel door must be equipped with a key locking device or an equivalent day locking device.

Completely enclosed masonry rooms or equivalents constructed after January 1, 1975, must be equipped with an electrical alarm system which, when unauthorized entry is attempted, transmits a signal directly to a central station protection company, or a local or state police agency which has a legal responsibility to respond, or a 24-hour control station operated by the registrant.

(b) Schedule IV and V Controlled Substance Stock shall be stored in a secure location within the pharmacy prescription compounding area or drug room.

Schedule IV and V Controlled Substance Stock stored within hospital clinical laboratories shall be kept in a separate secure locked location.

(c) Controlled Substance Stock within any such pharmacy shall not be accessible to other than specifically authorized pharmacy personnel, and shall be handled by authorized pharmacy personnel only.

(Effective July 27, 1984)

Sec. 21a-262-9. Hospital patient care areas, hospital nursing stations, other hospital drug storage locations, chronic and convalescent nursing homes, rest homes with nursing supervision, children's nursing homes, and areas and locations within correctional and/or juvenile training facilities, youth service facilities, mentally retarded facilities, and any other location other than pharmacies, hospital clinical laboratories, satellite pharmacies, or drug rooms, wherein drugs are stored, prepared, or dispensed not specifically referred to in section 21a-262-1 through section 21a-262-10 inclusive

(a) Schedule II Controlled Substances in small amounts not exceeding the quantity necessary for efficient operation kept at any specific individual area or location shall be stored in a locked substantially constructed nonportable and immobile metal cabinet or metal container within another separate locked enclosure. Keys shall not be the same for each of these locks and such keys shall be kept on two separated key rings or holders. Not more than one set of keys for the schedule II controlled substance cabinets shall be available to nonsupervisory personnel.

(b) At the beginning of each work period or shift, a nurse must be assigned responsibility for the security of schedule II controlled substance stock. Such responsibility shall be assumed by each said nurse who shall prepare a signed inventory indicating each kind and quantity of schedule II controlled substance received, the time and date received, and from whom received. This responsibility shall not be transferred or assigned to another nurse or person during the course of each work period or shift unless another signed inventory transferring responsibility is first prepared. For systems regulated under subsection (h) of this section, the requirements of this subsection shall be extended to include schedule III, IV and V controlled substance stock in addition to schedule II controlled substance stock.

(c) Schedule III, IV, V Controlled Substance Stock in small amounts not exceeding the quantity necessary for normal efficient operation of each individual unit shall be stored with Schedule II Controlled Substances in compliance with security measures as required per Section 21a-262-9 (a) or separately from other drugs and/or substances in a separate secure locked nonportable immobile substantially constructed cabinet or container. Access to such cabinet or container shall be limited to a minimum number of personnel essential for efficient operation.

(d) Schedule III, IV, V Controlled Substance Stock in small quantities intended for emergency use only, may be stored within an emergency drug kit or on emergency crash carts equipped with disposable locking or sealing devices, provided adequate security measures for such controlled substance stock are maintained and required record-keeping procedures are complied with.

(e) The same security requirements shall apply for controlled substances obtained pursuant to individual patient(s) prescriptions as for stock controlled substances as outlined under this section 21a-262-9 inclusive. Controlled substances obtained pursuant to such individual patient(s) prescriptions shall not be used for any other patient(s) and when no longer required for the intended specific individual patient, shall be securely kept and

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safeguarded until properly disposed of.

(f) In cases involving Unit Dose or experimental, trial, new, or innovative drug distribution procedures, the Commissioner of Consumer Protection may approve of other controlled substance(s) security safeguards for a specific time period, in lieu of any required by section 21a-262-1 through section 21a-262-10 inclusive, on an individual basis after evaluating each such drug distribution procedure. Such approval may be extended indefinitely by said Commissioner upon such successful completion of the trial period. If approval is not given by said Commissioner prior to the implementation of any such drug distribution procedure, controlled substance security requirements as outlined in section 21a-262-1 through section 21a-262-10 inclusive shall apply.

(g) Where unwanted partial or individual doses of Controlled Substances are discarded by nursing personnel, a record of each such destruction must be made indicating the date and time of each such destruction; the name, form, strength, and quantity of Controlled Substance destroyed; the signature of the nurse destroying the Controlled Substance, and the signature of another nurse who witnesses such destruction. In other than hospital locations, an authorized person may witness such destruction.

(h) In cases involving distribution of an individual patient's controlled substance medication by means of the use of mobile medication carts within chronic and convalescent nursing homes, and rest homes with nursing supervision, the following security safeguards shall be approved in lieu of any required by section 21a-262-9 (a) and (c); except that compliance with this subsection shall not be required of a facility using a mobile medication cart system previously approved for use in that facility by the commissioner of consumer protection. Compliance with this subsection by facilities with previously approved systems shall be in lieu of the requirements of such previously approved systems.

(1) Mobile medication carts shall be of substantial construction and shall incorporate the following security features:

(A) A separate, lockable, non-removable drawer or compartment for storage of all controlled substances,

(B) The key which locks the controlled substance drawer or compartment shall be different from the key(s) to all other locking devices on each cart and such keys shall not be interchangeable between carts within the same facility, and

(C) Locking mechanism(s) which will secure the entire contents of the cart without requiring the use of a key;

(2) Mobile medication carts when not in use shall be locked and stored within a limited access locked and enclosed medication room or closet or other substantially constructed enclosed structure;

(3) Mobile medication carts shall be securely locked at all times when unattended. All medication and injection equipment shall be stored within the locked cart. Locking devices shall be maintained in good working order;

(4) The separate controlled substance drawer or compartment shall be securely locked at all times except for the actual time required to remove or replace needed items or to

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conduct an audit;

(5) The keys to the controlled substance drawer or compartment of each mobile cart shall be separated from the keys to the other locking devices of that cart and shall be carried personally by the nurse responsible for the required controlled substance audit during each nursing shift and no duplicate keys shall be available to other than specifically designated supervisory personnel;

(6) Requirements of section 21a-262-9 (b) concerning audits of controlled substance stocks shall be extended to include schedule III, IV, and V controlled substance stock in addition to schedule II controlled substance stock;

(7) Record keeping entries of controlled substances administered shall be made at the time of administration;

(8) The director of nursing or his/her nursing supervisor designee shall conduct unannounced documented audits of all controlled substance stocks on all units at least twice a month; and

(9) All controlled substance medications shall be inventoried when received and immediately placed into the controlled substance drawer or compartment within the mobile cart. Quantities of patients' controlled substance medications stored within mobile medication carts shall be limited to the minimum quantities necessary to provide for normal efficient operation and shall be promptly removed for proper disposition when no longer needed by the patient.

(i) In cases involving distribution of an individual patient's controlled substance medication by means of the use of mobile medication carts within chronic and convalescent nursing homes, and rest homes with nursing supervision, other security safeguards in lieu of any required by section 21a-262-9 (h) may be approved by the commissioner of consumer protection on an individual basis after evaluating the drug distribution procedure of the applicant for approval pursuant to this subsection.

(Effective July 27, 1984)

Sec. 21a-262-10. Industrial health facilities, educational institution infirmaries, clinics, summer camps, and other institutions or establishments providing health care services including those which are group, private, state, and/or municipally operated

(a) Schedule II and III Controlled Substance Stock, if No. 15 controlled substance units or less shall be stored separate from other drugs and substances in a separate secure substantially constructed locked metal or wood cabinet.

Schedule II and III Controlled Substance Stock if in excess of No. 15 controlled substance units shall be stored in an approved safe.

(b) Schedule IV and V Controlled Substance Stock shall be stored in a separate secure locked location or with Schedule II and III Controlled Substances in compliance with security measures as required per section 21a-262-10 (a).

(c) Controlled Substances for Stock use shall be purchased or obtained by the medical

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director or physician in charge from a wholesaler or manufacturer of drugs, and shall be handled only by an authorized physician, Connecticut licensed pharmacist, or Connecticut licensed nurse. Controlled substances shall be the property of the medical director or physician in charge who shall be responsible for security requirements and record keeping procedures.

(d) The same security requirements shall apply for controlled substances obtained pursuant to patient(s) prescriptions as for stock controlled substances. Controlled substances obtained pursuant to such individual patient(s) prescriptions shall not be used for any other patient(s) and when no longer required for the intended specific individual patient shall be securely kept and safeguarded until properly disposed of.

(Effective July 27, 1984)

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Subject

Drug Enforcement and Safe Neighborhood Programs

Inclusive Sections

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Sec. 21a-274a-10.	Supplanting of local funds prohibited (Repealed)
Sec. 21a-274a-11.	Compliance (Repealed)
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Drug Enforcement and Safe Neighborhood Programs

Sec. 21a-274a-1. Drug enforcement program definitions (Repealed)

Repealed June 11, 2014.

(Adopted effective January 31, 1994; Amended April 18, 1996; Amended June 29, 1998; Amended February 24, 2000; Amended June 26, 2001; Amended August 5, 2003; Repealed June 11, 2014)

Notes: For 2014 repeal, see Sec. 54 of Public Act 14-187. (June 11, 2014)

Sec. 21a-274a-2. Drug enforcement program description (Repealed)

Repealed June 11, 2014.

(Adopted effective January 31, 1994; Amended April 18, 1996; Amended June 29, 1998; Amended February 24, 2000; Amended June 26, 2001; Amended August 5, 2003; Amended November 15, 2004; Repealed June 11, 2014)

Notes: For 2014 repeal, see Sec. 54 of Public Act 14-187. (June 11, 2014)

Sec. 21a-274a-3—21a-274a-4. Repealed

Repealed August 5, 2003.

Sec. 21a-274a-5. Safe neighborhoods program description (Repealed)

Repealed June 11, 2014.

(Adopted effective January 31, 1994; Amended April 18, 1996; Repealed June 11, 2014)

Notes: For 2014 repeal, see Sec. 54 of Public Act 14-187. (June 11, 2014)

Sec. 21a-274a-6. Safe neighborhoods program funding and eligibility (Repealed)

Repealed June 11, 2014.

(Adopted effective January 31, 1994; Amended April 18, 1996; Amended February 24, 2000; Amended November 15, 2004; Repealed June 11, 2014)

Notes: For 2014 repeal, see Sec. 54 of Public Act 14-187. (June 11, 2014)

Sec. 21a-274a-7. Guidelines for safe neighborhoods program components (Repealed)

Repealed June 11, 2014.

(Adopted effective January 31, 1994; Amended April 18, 1996; Repealed June 11, 2014)

Notes: For 2014 repeal, see Sec. 54 of Public Act 14-187. (June 11, 2014)

Sec. 21a-274a-8. Application due date and process (Repealed)

Repealed June 11, 2014.

(Adopted effective January 31, 1994; Amended April 18, 1996; Repealed June 11, 2014)

Notes: For 2014 repeal, see Sec. 54 of Public Act 14-187. (June 11, 2014)

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Sec. 21a-274a-9. Safe neighborhoods program review criteria and process (Repealed)

Repealed June 11, 2014.

(Adopted effective January 31, 1994; Amended April 18, 1996; Repealed June 11, 2014)

Notes: For 2014 repeal, see Sec. 54 of Public Act 14-187. (June 11, 2014)

Sec. 21a-274a-10. Supplanting of local funds prohibited (Repealed)

Repealed June 11, 2014.

(Adopted effective January 31, 1994; Amended April 18, 1996; Repealed June 11, 2014)

Notes: For 2014 repeal, see Sec. 54 of Public Act 14-187. (June 11, 2014)

Sec. 21a-274a-11. Compliance (Repealed)

Repealed June 11, 2014.

(Adopted effective January 31, 1994; Amended April 18, 1996; Repealed June 11, 2014)

Notes: For 2014 repeal, see Sec. 54 of Public Act 14-187. (June 11, 2014)

Sec. 21a-274a-12. Involuntary termination of grants (Repealed)

Repealed June 11, 2014.

(Adopted effective January 31, 1994; Amended April 18, 1996; Repealed June 11, 2014)

Notes: For 2014 repeal, see Sec. 54 of Public Act 14-187. (June 11, 2014)

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Supportive Personnel in Pharmacies

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Sec. 21a-308-1—21a-308-8. Repealed

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Supportive Personnel in Pharmacies

Sec. 21a-308-1—21a-308-8. Repealed

Repealed January 11, 1999.

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Subject

Registration of Practitioners for Controlled Substances

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Registration of Practitioners for Controlled Substances

Sec. 21a-326-1. Definitions

(a) “Abuse or Excessive Use of Drugs” means the personal use of controlled substances by a practitioner or other registrant in such dosage and frequency not warranted by an existing medical condition or use of controlled substances solely for a stimulant, depressant, or hallucinogenic effect which use is not within the medical consensus or stated in the medical literature as acceptable or proper.

(b) “Controlled Substance Schedules” means the grouping of drugs, schedules 1 through 5, as delineated in Section 21a-242 of Chapter 420b, Connecticut General Statutes or in regulations promulgated under the Code of Federal Regulation. Any particular controlled substance shall be deemed to be in the schedule wherein such controlled substance appears by its chemical or generic name within Sec. 21a-242 of Chapter 420b, Connecticut General Statutes or in regulations promulgated under the Code of Federal Regulation.

(c) “Course of Professional Practice” means the limitation of prescribing, dispensing, or administering of controlled substances for professional treatment authorized pursuant to regulations and/or statutes of the appropriate state licensing authority under which situations there must be a bona fide practitioner-patient relationship. The prescribing or dispensing of controlled substances for patients, friends, relatives, associates, and/or employees wherein a bona fide practitioner-patient relationship does not exist or wherein the practitioner has not medically evaluated the need for controlled substances shall not be considered to be in the “course of professional practice.”

(d) “Effective Controls Against Diversion” means the implementation of the following controls on a regular basis necessary for the prevention of diversion of controlled substances:

(1) Prescribing, dispensing, or administering of controlled substances only after a proper medical evaluation.

(2) Maintaining of controlled substance record keeping and security requirements pursuant to Chapter 420b of the Connecticut General Statutes.

(3) Providing for adequate security of prescription blanks to prevent thefts and/or illegal use.

(4) Regular monitoring of patient(s) conditions in instances wherein continued or prolonged treatment with controlled substances is indicated.

(5) Refraining from knowingly prescribing controlled substances for persons abusing such controlled substances and/or using such controlled substances for purposes of maintenance of drug dependency unless pursuant to state and federal regulations pertaining to treatment of drug dependent persons.

(6) Compliance with all state and federal statutes and regulations concerning controlled substances.

(e) “Therapeutic or Other Proper Medical or Scientific Purposes” means the following:

(1) The prescribing, dispensing, or administering of a controlled substance for treatment of a specific disease or medical condition, recognized by medical consensus and/or stated in the literature of the manufacturers of the controlled substances as being the purposes for

which the controlled substance is intended.

(2) Investigational use of a controlled substance by a researcher or scientist wherein documentation of necessity of use of such controlled substances is maintained.

(f) "Legend drug" is any article, substance, preparation or device which bears the legend: "CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT A PRESCRIPTION."

(Effective July 27, 1984)

Sec. 21a-326-2. Registration applications and renewals

Registration applications and renewals shall be on such forms as furnished by the Commissioner of Consumer Protection and shall whenever so indicated be signed by the applicant.

(a) All registration applications shall contain all information required by the Commissioner of Consumer Protection. Applications not inclusive of required data or those which are illegibly executed may be returned for correction.

(b) It shall be the responsibility of all practitioners, hospitals, or other institutions who propose to engage in distributing, prescribing, administering, dispensing, or using any controlled substance within this state to submit an application for registration with the appropriate fee to the Commissioner of Consumer Protection. The Commissioner shall issue a certificate of registration in accordance with the provisions of Chapter 420c of the General Statutes.

(c) It shall be the responsibility of the applicant to submit his/her registration renewal application to the Commissioner at least one month prior to the expiration of his/her current registration.

(d) All practitioners, hospitals, clinics, or other authorized persons or facilities wishing to prescribe, administer, or dispense controlled substances shall obtain a certificate of registration issued by the commissioner of consumer protection as mated by Section 21a-317 of the General Statutes. No controlled substance shall be prescribed, administered, or dispensed until such registration has been approved by the commissioner. Regulation fees shall not be prorated.

(e) For registration purposes applicants shall be classified as follows:

- (1) Practitioner;
- (2) Hospital;
- (3) Clinic;
- (4) Others.

All practitioners shall designate their specific professional practice; e.g., M.D., dentist, veterinarian, osteopath or podiatrist on their application for registration. Other applicants shall designate their appropriate title; i.e., Ph.D., Director, Director of Pharmacy, Administrator, President, Manager, etc.

(Effective July 27, 1984)

Sec. 21a-326-3. Notification of failure to obtain or renew registration

The Commissioner of Consumer Protection shall notify the Federal Drug Enforcement Administration or its successor, of the failure of any practitioner or researcher to obtain or renew a valid state registration; or of any administrative action taken by the Commissioner resulting in the denial, surrender, suspension, or revocation of a registration or the limitation of the controlled substance schedules of a registration.

(Effective July 27, 1984)

Sec. 21a-326-4. Responsibility of registrant

(a) It shall be the responsibility of a registrant who ceases to practice or who goes out of business to notify the Commissioner in writing five (5) days before such occurrence.

(b) It shall be the responsibility of the registrant to notify the Commissioner within thirty (30) days of any changes in information or data required on the registration application pursuant to which any registration is issued.

(Effective July 27, 1984)

Sec. 21a-326-5. Registration of controlled substances

(a) It shall be the responsibility of the registrant to be registered in accordance with state and federal controlled substance laws for those particular controlled substance schedules incorporating those drugs used or to be used within the scope of his/her professional practice.

(b) A registrant may voluntarily surrender his/her controlled substance registration privileges in any or all controlled substance schedules to the Commissioner of Consumer Protection or may voluntarily refrain from registering in those controlled substance schedules not applicable to his/her professional practice or scientific research.

(c) The Commissioner of Consumer Protection may in accordance with Sections 21a-323 and 21a-324 of the General Statutes limit the schedules for which the practitioner is registered.

(Effective July 27, 1984)

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Banned Hazardous Substances

Section

§ 21a-336-1

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Sec. 21a-336-1. Banned hazardous substances

Banned Hazardous Substances

Sec. 21a-336-1. Banned hazardous substances

Under authority of General Statutes, Section 21-336 (c), the Commissioner of Consumer Protection declares as a banned hazardous substance the following articles because the degree or nature of the hazard involved in the presence or use of such articles is such that labeling adequate to protect the public health and safety cannot be devised. As a banned hazardous substance, such articles shall be removed from commerce as of the effective date of each Subsection:

(a) products containing butyl nitrite intended, or packaged in a form suitable, for use in a household as an odorant, deodorant, air freshener, odorizer or for any other purpose whereby such products are intended, or their primary functional purpose is, to be breathed, inhaled or sniffed;

(b) any paint or other similar surface-coating materials for consumer use that contain lead or lead compounds and in which the lead content (calculated as lead metal) is in excess of 0.06 percent of the weight of the total nonvolatile content of the paint or the weight of the dried paint film;

(c) Obsolete.

(d) any stuffed toy consisting of cotton, wool, hair, feathers, down, rubber, foam, man-made or manufactured fibers, or miscellaneous fibers which contains any detectable level of kerosene, as determined by the application of the best technology available;

(e) any stuffed toy consisting of cotton, wool, hair, feathers, down, rubber, foam, man-made or manufactured fibers, or miscellaneous fibers which contains any detectable level of polychlorinated biphenals (pcb's), as determined by the application of the best technology available.

(Effective August 25, 1986)

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Residential Stair Lift Technician's License

Inclusive Sections

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Residential Stair Lift Technician's License

Sec. 21a-340f-1. Definitions

(1) "Apprentice trainee" means any person registered with the Department of Consumer Protection for the purpose of learning a skilled trade.

(2) "Private residence" means a residential dwelling containing a residential stair lift that is not intended for general public use.

(3) "Residential stair lift" means an inclined residential stairway chair lift with a fixed in place swivel single seat and its internal components, installed in or at a private residence.

(4) "Residential stair lift work" means the installation, repair, replacement, maintenance or alteration of residential stair lifts installed in or at a private residence for use on a stairway structure capable of safely supporting the loads imposed on such structure. Residential stair lift work does not include non-structural or cosmetic work on a residential stair lift.

(Effective April 17, 2017)

Sec. 21a-340f-2. Qualifications to obtain licensure

A residential stair lift technician license may be issued by the Department of Consumer Protection to any applicant registered as an apprentice trainee with the department who (1) has experience performing residential stair lift work of not less than ten new installations, (2) has completed a training program of instruction, which shall include, but need not be limited to, a review of applicable state and federal laws, codes, standards and work site safety requirements of not less than twenty hours related to residential stair lift work, which program has been reviewed and approved by the Commissioner of Consumer Protection, and (3) has paid the license fee specified in section 20-340f of the Connecticut General Statutes to the department.

(Effective April 17, 2017)

Sec. 21a-340f-3. License Transferability

Licenses issued to residential stair lift technicians shall not be transferable or assignable and the failure to receive a notice of expiration or a renewal application for a license shall not exempt a residential stair lift technician from the obligation to renew said license.

(Effective April 17, 2017)

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Subject

Repurchase of Banned Hazardous Substances

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Repurchase of Banned Hazardous Substances

Sec. 21a-342-1. Repurchase of banned hazardous substances

(a) **Scope.** This section establishes the procedures under which a banned hazardous article or substance which is required to be repurchased under Section 21a-346 of the Act shall be repurchased.

(b) **Definitions.** For the purposes of this section:

(1) The term “manufacturer” includes any person who manufactures or imports an article or substance for distribution or sale in the State of Connecticut, except that in the case of an article or substance distributed or sold under a name other than that of the actual manufacturer of the article or substance, the term “manufacturer” includes any person under whose name the article or substance is distributed or sold.

(2) The term “distributor” includes any person who sells an article or substance at wholesale.

(3) The term “dealer” includes any person who sells an article or substance at retail. A dealer who sells at wholesale an article or substance subject to this section shall, with respect to that sale, be considered the distributor of that article or substance.

(4) The term “person” includes an individual, partnership, corporation or association, or his or its legal representative or agent.

(5) The term “purchase price” means the amount of money paid to acquire an article or substance, including all taxes, but excluding transportation or shipping costs and finance, interest, or service charges.

(6) The term “reasonable and necessary transportation charges,” when used in connection with the return of an article or substance to a dealer, means:

(i) The actual costs incurred in returning the product in any manner reasonably specified by the dealer, including personal conveyance; or

(ii) The actual costs incurred in returning the product by mail, commercial carrier, or any other manner, including personal conveyance, reasonably utilized in the absence of specific instructions by the dealer.

(7) The term “reasonable and necessary expense” when used in connection with the return of an article or substance to a distributor or manufacturer shall include the cost of labor, administration, and transportation in the handling, processing, and shipping of that product.

(c) **Dealers.** In the case of a person who has purchased an article or substance from a dealer and who returns it to that dealer, the dealer shall refund the purchase price paid and reimburse the purchaser for any reasonable and necessary transportation charges incurred in its return.

(d) **Distributors.** The distributor of the article or substance shall repurchase it from the person to whom the distributor sold it and shall:

(1) Refund that person the purchase price paid for the article or substance;

(2) If that person has repurchased the article or substance under paragraph (c) of this section, reimburse that person for any reasonable and necessary transportation charges paid in accordance with that paragraph for the return of the article or substance in connection

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with its repurchase; and

(3) If the distributor requires the return of the article or substance in connection with the distributor's repurchase of it in accordance with this paragraph, reimburse that person for any reasonable and necessary expenses incurred in returning it to the distributor.

(e) **Manufacturers.** The manufacturer of the article or substance shall repurchase it from the person to whom the manufacturer sold it and shall:

(1) Refund that person the purchase price paid for the article or substance;

(2) Reimburse that person for any reasonable and necessary transportation charges and expenses paid by that person in connection with repurchase under paragraph (c) or (d) of this section; and

(3) If the manufacturer requires the return of the article or substance in connection with the manufacturer's repurchase of it in accordance with this paragraph, reimburse that person for any reasonable and necessary expenses incurred in returning it to the manufacturer.

(f) Notice of banned article or substance subject to repurchase.

(1) As soon as the manufacturer of an article or substance knows or receives information from which the manufacturer should know that the article or substance is a banned hazardous substance, the manufacturer shall immediately notify each distributor, dealer, and other person to whom the manufacturer has sold that product that it is a banned hazardous substance subject to repurchase under the act. This notice will identify the article or substance involved (including model number or other distinguishing characteristics), set forth the nature of the hazards involved in the use of the product, provide instructions for return or other disposition of the product, and advise that any distributor or dealer who receives the notice is required to provide further notice as specified in this paragraph. As soon as the distributor receives such notice, that distributor shall, in the same manner, similarly notify each distributor, dealer, and other person to whom the distributor has sold the article or substance.

(2) A dealer who sells or has sold an article or substance at a retail establishment shall, upon notification that such product is a banned hazardous substance, immediately do the following:

(i) Prepare and prominently display a list captioned "Banned Articles or Substances List" which shall contain an identification of the banned product including the model number or other distinguishing characteristics, the name and address of the manufacturer, the date notice was received from the manufacturer or distributor, and the nature of the hazards involved with the use of that product. Each banned article or substance shall be maintained on the list for a period of not less than 120 days from the date the dealer received the notification. The list will be considered to be prominently displayed if it is available for inspection at a convenient location in the store, to which the public has access without having to obtain the permission or assistance of a store employee, and if a sign posted in accordance with the provisions of subdivision (iii) of this subparagraph clearly indicates the location of the list.

(ii) Prepare and prominently display a notice captioned "Notice of Refund Procedures

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for Banned Articles or Substances.” This notice shall be displayed for a period of not less than 120 days from the date the dealer received the latest notification. The notice will be considered to be prominently displayed if it is available for inspection at the same convenient location in the store as the banned articles or substances list prepared in accordance with subdivision (i) of this subparagraph, to which the public has access without having to obtain the permission or assistance of a store employee, and if a sign posted in accordance with subdivision (iii) of this subparagraph clearly indicates the location of the list. The notice of refund procedures shall take following format:

Notice of Refund Procedures for Banned Articles or Substances

If you have purchased any product on the accompanying list of banned articles or substances, return that product to the retail dealer from whom you purchased it and you will receive a refund of the price which you paid for the product and any reasonable and necessary transportation charges incurred in the return of the product.

“Reasonable and necessary transportation charges” include: (1) the actual cost of returning the product in any manner reasonably specified by the dealer, including personal conveyance; or (2) the actual costs incurred in returning the product by mail, commercial carrier, or any other manner, including personal conveyance, reasonably utilized in the absence of specific instructions by the dealer.

(At this place, the retailer may specify the means to be used to return any product on the list purchased from that retailer.)

(iii) Prepare and prominently display a sign captioned “BANNED ARTICLES OR SUBSTANCES LIST AND REPURCHASE PROCEDURES.” This sign shall be posted on each floor of each store or other establishment open to the public where items similar to the banned product are displayed or sold. Each sign shall be not less than 22 inches by 28 inches in size, shall be printed in color contrasting with the background, and shall be so displayed for a period of not less than 120 days from date the dealer received the latest notification. Each sign shall contain the following language:

Banned Articles or Substances List and Repurchase Procedures

A list of products sold by this store which have been identified as banned articles or substances under the State Child Protection Act by the Connecticut Department of Consumer Protection is available for inspection at (describe location of list).

These products should not be used.

The products which appear on this list may be returned for refund as specified in the “Notice of Refund Procedures” which is posted at the same location as the list.

(3) In the case of an article or substance sold at retail other than in a retail establishment, the dealer, upon notification that the product is a banned article or substance, shall publicize a clear and conspicuous “Notice of Banned Article or Substance,” as follows, in a manner

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reasonably calculated to reach as many purchasers of the banned product as practicable:

Notice of Banned Article or Substance

The Connecticut Department of Consumer Protection has identified the following as a banned article or substance under the State Child Protection Act: (insert identification of banned product including model number or other distinguishing characteristics and the name and address of manufacturer).

This product should not be used because (describe nature of hazards associated with the use of the product).

If you have purchased this product, return the product to the retail dealer from whom you purchased it and you will receive a refund of the price which you paid for the product and any reasonable and necessary transportation charges incurred in its return.

If you purchased the product described in this notice from (insert name and address of retailer publishing this notice), return the product to this firm at the address listed above by (specify means of transportation to be utilized) to receive a refund of your purchase price and transportation charges.

(g) Any person subject to the jurisdiction of the State Child Protection Act, Chapter 420d of the General Statutes, who has complied with any administrative or court order issued pursuant to regulations promulgated under the Federal Consumer Product Safety Act, the Consumer Product Safety Improvement Act, and the Federal Flammable Fabrics Act, concerning the repurchase of banned hazardous substances shall be deemed to be in compliance with the rules and regulations of the Connecticut Department of Consumer Protection concerning the repurchase of banned hazardous substances.

(Effective July 27, 1984)

Sec. 21a-342-2. Warning label concerning small parts

(a) **Scope.** This section establishes the standards for the warning label that is required by Section 21a-337 (10) of the State Child Protection Act. Toys or other articles which are exempted by 16 CFR 1501.3 and paper, fabric, yarn, fuzz, elastic and string are exempted from the provisions of this section.

(b) **Content.** The warning label shall contain:

(1) the signal word “Warning”; and

(2) a statement of hazard that warns that the contents include small parts which pose a hazard for children under the age of three.

(c) **Conspicuousness.** The warning label shall be printed as follows:

(1) The warning label shall appear in conspicuous and legible type which is in contrast by typography, layout or color with the other printed matter on the packaging material;

(2) the type size of the warning label shall comply with the requirements of 16 CFR 1500.121 (c) (2); and

(3) the warning label shall not appear on the bottom or back panel of the packaging material. The bottom or back panel shall be determined by the manufacturer’s intended display position of the product for retail sale.

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(d) Unpackaged Toys and Articles. The warning label for toys or other articles which are unpackaged, such as items sold in bulk or by vending machine, and which are too small to have a warning label attached to the item, shall be placed on the container from which the items are sold or the vending machine displaying the toy or article.

(Effective May 21, 1993)

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Palliative Use of Marijuana

Sec. 21a-408-1. Definitions

As used in sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies:

(1) “Abuse of drugs” means the use of controlled substances solely for their stimulant, depressant or hallucinogenic effect upon the higher functions of the central nervous system and not as a therapeutic agent prescribed in the course of medical treatment or in a program of research operated under the direction of a physician or pharmacologist;

(2) “Act” means Sections 21a-408 to 21a-408q, inclusive, of the Connecticut General Statutes;

(3) “Administer” means the direct application of marijuana to the body of a qualifying patient by inhalation, ingestion or any other means;

(4) “Adulterated” has the same meaning as described in section 21a-105 of the Connecticut General Statutes;

(5) “Advertisement” means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of marijuana;

(6) “Agent” means an authorized person who acts on behalf of or at the direction of another person. It does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman;

(7) “Approved safe” has the same meaning as described in section 21a-262-1 of the Regulations of Connecticut State Agencies;

(8) “Approved vault” has the same meaning as described in section 21a-262-1 of the Regulations of Connecticut State Agencies;

(9) “Batch” means a specific harvest of marijuana or marijuana products that are identifiable by a batch number, every portion or package of which is uniform within recognized tolerances for the factors that were subject to a laboratory test and that appear in the labeling;

(10) “Board” means the Board of Physicians appointed under the provisions of section 21a-408l of the Connecticut General Statutes;

(11) “Bona fide physician-patient relationship” means a relationship in which the physician has ongoing responsibility for the assessment, care and treatment of a patient’s debilitating medical condition, or a symptom of the patient’s debilitating medical condition, for which the physician has certified to the department that the patient would benefit from the palliative use of marijuana;

(12) “Commissioner” means the Commissioner of Consumer Protection;

(13) “Compounding” means to combine, mix or put together two or more ingredients and includes the preparation of a marijuana product in anticipation of a qualifying patient, primary caregiver or physician request;

(14) “Controlled substance” means a drug, substance, or immediate precursor listed in sections 21a-243-7 through 21a-243-11, inclusive, of the Regulations of Connecticut State

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(15) “Cultivation” has the same meaning as provided in section 21a-408 of the Connecticut General Statutes;

(16) “Debilitating” means a chronic medical condition that causes weakness or impairs the strength or ability of an individual and has progressed to such an extent that it substantially limits one or more major life activities of such individual. An assessment of whether a major life activity has been substantially limited shall be guided by interpretations of the term “disability” as set forth in 42 USC 12102(1)(A);

(17) “Debilitating medical condition” has the same meaning as provided in section 21a-408 of the Connecticut General Statutes;

(18) “Deliver” or “delivery” means the actual, constructive or attempted transfer from one person to another of marijuana, whether or not there is an agency relationship;

(19) “Department” means the Department of Consumer Protection;

(20) “Dietary supplement” has the same meaning as provided in 21 U.S.C. 321;

(21) “Dispensary” has the same meaning as provided in section 21a-408 of the Connecticut General Statutes;

(22) “Dispensary department” means that area within a dispensary facility where marijuana is stored, dispensed and sold. If a dispensary facility does not offer any products or services other than marijuana and paraphernalia, the entire dispensary facility is a dispensary department for purposes of sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies;

(23) “Dispensary facility” means a place of business where marijuana may be dispensed or sold at retail to qualifying patients and primary caregivers and for which the department has issued a dispensary facility license to an applicant under the Act and section 21a-408-14 of the Regulations of Connecticut State Agencies;

(24) “Dispensary facility backer” means, except in cases where the dispensary is the sole proprietor of a dispensary facility, any person with a direct or indirect financial interest in a dispensary facility, except “dispensary facility backer” does not include a person with an investment interest in a dispensary facility provided the interest held by such person and such person’s co-workers, employees, spouse, parent or child, in the aggregate, do not exceed five per cent of the total ownership or interest rights in such dispensary facility and such person does not participate directly or indirectly in the control, management or operation of the dispensary facility;

(25) “Dispensary facility manager” means the dispensary who has complete control and management over the dispensary facility;

(26) “Dispensary facility employee” means a dispensary, dispensary technician, dispensary facility staff and all other persons employed by a dispensary facility or who otherwise have access to the dispensary facility, including independent contractors who are routinely on the facility premises;

(27) “Dispensary technician” means an individual who has had an active pharmacy technician registration in Connecticut within the past five years, is affiliated with a licensed

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dispensary and is registered with the department in accordance with section 21a-408-24 of the Regulations of Connecticut State Agencies;

(28) “Dispense” or “dispensing” means those acts of processing marijuana for delivery or for administration for a qualifying patient pursuant to a written certification consisting of:

(A) Comparing the directions on the label with the instructions on the written certification, if any, to determine accuracy;

(B) the selection of the appropriate marijuana product from stock;

(C) the affixing of a label to the container; and

(D) the provision of any instructions regarding the use of the marijuana;

(29) “Dispensing error” means an act or omission relating to the dispensing of marijuana that results in, or may reasonably be expected to result in, injury to or death of a qualifying patient or results in any detrimental change to the medical treatment for the patient;

(30) “Disqualifying conviction” means a conviction for the violation of any statute or regulation pertaining to the illegal manufacture, sale or distribution of a controlled substance or controlled substance analog unless the violation resulting in the conviction occurred when the person held a valid license or registration certificate from the department and the violation was of a federal statute or regulation related to the possession, purchase or sale of marijuana that is authorized under the Act and sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies;

(31) “Drug Control Division” means the division within the department responsible for overseeing the medical marijuana program;

(32) “Drug” has the same meaning as provided in section 20-571 of Connecticut General Statutes;

(33) “Electronic data intermediary” means an entity that provides the infrastructure that connects the computer systems or other electronic devices utilized by dispensaries with those used by physicians or the department in order to facilitate the secure transmission of qualifying patient or primary caregiver information;

(34) “Financial interest” means any actual, or a future right to, ownership, investment or compensation arrangement with another person, either directly or indirectly, through business, investment or family. “Financial interest” does not include ownership of investment securities in a publicly-held corporation that is traded on a national exchange or over-the-counter market, provided the investment securities held by such person and such person’s co-workers, employees, spouse, parent or child, in the aggregate, do not exceed one-half of one per cent of the total number of shares issued by the corporation;

(35) “Forms” means applications, registrations, written certifications or other documents prescribed by the commissioner in either hardcopy or electronic format;

(36) “Good standing” means a person has a license or registration with the department that is not on probation or subject to any other restriction or oversight by the department beyond others in the same class;

(37) “Label” means a display of written, printed or graphic matter upon the immediate

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container of any product containing marijuana;

(38) “Laboratory” means a laboratory located in Connecticut that is licensed by the department to provide analysis of controlled substances pursuant to section 21a-246 of the Connecticut General Statutes;

(39) “Legend drug” has the same meaning as provided in section 20-571 of the Connecticut General Statutes;

(40) “Manufacture” or “manufacturing” means any process by which marijuana is converted to a marijuana product and that involves heating, mixing marijuana with any other ingredient or otherwise altering the raw material;

(41) “Marijuana” has the same meaning as provided in section 21a-240 of the Connecticut General Statutes;

(42) “Marijuana product” means any product containing marijuana, including raw materials, that requires no further processing and that is packaged for sale to dispensaries, qualifying patients and primary caregivers;

(43) “One-month supply” means the amount of marijuana reasonably necessary to ensure an uninterrupted availability of supply for a thirty-day period for qualifying patients, which amounts, including amounts for topical treatments, shall be determined by the commissioner on the basis of practical administration of the Act, available research and recommendations from the Board of Physicians;

(44) “Palliative use” has the same meaning as provided in section 21a-408 of the Connecticut General Statutes;

(45) “Paraphernalia” has the same meaning as provided in section 21a-408 of the Connecticut General Statutes;

(46) “Person” includes any corporation, limited liability company, association or partnership, or one or more individuals, government or governmental subdivisions or agency, estate, trust, or any other legal entity;

(47) “Pesticide chemical” has the same meaning as provided in section 21a-92 of the Connecticut General Statutes;

(48) “Petition” means a written request submitted pursuant to the Act and section 21a-408-12 of the Regulations of Connecticut State Agencies that recommends adding a medical condition, medical treatment or disease to the list of debilitating medical conditions that qualify for the palliative use of marijuana;

(49) “Pharmaceutical grade marijuana” means marijuana or marijuana products that are not adulterated and are:

(A) processed, packaged and labeled according to the Food and Drug Administration’s “Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements,” 21 CFR 111;

(B) labeled with the results of an active ingredient analysis, a microbiological contaminants analysis, a mycotoxin analysis, a heavy metal analysis and a pesticide chemical residue analysis which have been completed on a batch basis by a laboratory; and

(C) where each step of the production, cultivating, trimming, curing, manufacturing,

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processing and packaging method has been documented by using established standard operation procedures approved by the commissioner;

(50) “Pharmacist” has the same meaning as provided in section 20-571 of Connecticut’s General Statutes;

(51) “Pharmacy technician” has the same meaning as provided in section 20-571 of the Connecticut General Statutes;

(52) “Physician” has the same meaning as provided in section 21a-408 of the Connecticut General Statutes;

(53) “Prescription monitoring program” means the electronic prescription drug monitoring program established by section 21a-254(j) of the Connecticut General Statutes;

(54) “Primary caregiver” or “caregiver” has the same meaning as provided in section 21a-408 of the Connecticut General Statutes for “primary caregiver”;

(55) “Producer” has the same meaning as provided in section 21a-408 of the Connecticut General Statutes;

(56) “Producer backer” means any person with a direct or indirect financial interest in an entity licensed as a producer, except it shall not include a person with an investment interest in a producer, provided the interest held by such person and such person’s co-workers, employees, spouse, parent or child, in the aggregate, does not exceed five per cent of the total ownership or interest rights in such producer and such person does not participate directly or indirectly in the control, management or operation of the production facility;

(57) “Production” or “produce” means the manufacture, planting, preparation, cultivation, growing, harvesting, propagation, compounding, conversion or processing of marijuana, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container, except that this term does not include the preparation or compounding of marijuana by a patient or caregiver for the patient’s use;

(58) “Production facility” means a secure, indoor facility where the production of marijuana occurs and that is operated by a person to whom the department has issued a producer license under the Act and sections 21a-408-20 of the Regulations of Connecticut State Agencies;

(59) “Production facility employee” means any person employed by a producer or who otherwise has access to the production facility, including independent contractors who are routinely on the production facility premises;

(60) “Qualifying patient” or “patient” has the same meaning as provided in section 21a-408 of the Connecticut General Statutes;

(61) “Registration certificate” means an identification card or other document issued by the department that identifies a person as a registered qualifying patient or primary caregiver;

(62) “Sale” is any form of delivery, which includes barter, exchange or gift, or offer therefor, and each such transaction made by any person whether as principal, proprietor,

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agent, servant or employee;

(63) “State”, when applied to a part of the United States, includes any state, district, commonwealth, territory or insular possession thereof, and any area subject to the legal authority of the United States of America;

(64) “Usable marijuana” has the same meaning as provided in section 21a-408 of the Connecticut General Statutes; and

(65) “Written certification” means a written or electronically submitted statement issued by a physician to the department certifying a patient for the palliative use of marijuana, which shall be submitted on a form and in a manner prescribed by the commissioner.

(Effective September 6, 2013)

Sec. 21a-408-2. Physician requirements for issuing written certifications to the department

(a) The department shall only accept written certifications from physicians for the palliative use of marijuana when the physician:

(1) Holds an active license under chapter 370 of the Connecticut General Statutes and is in good standing;

(2) Holds an active department controlled substance practitioner registration, is in good standing and is eligible to prescribe schedule II controlled substances;

(3) Holds an active federal Drug Enforcement Administration controlled substance registration, is in good standing and is eligible to prescribe schedule II controlled substances;

(4) Is registered with, and able to access, the Prescription Monitoring Program; and

(5) Is not engaged in any conduct prohibited by the Act or sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies.

(b) A physician issuing a written certification shall:

(1) Have a bona fide physician-patient relationship with the qualifying patient;

(2) Conduct an assessment and evaluation of the patient in order to develop a treatment plan for the patient, which shall include an examination of the patient and the patient’s medical history, prescription history and current medical condition, including an in-person physical examination;

(3) Diagnose the patient as having a debilitating medical condition;

(4) Be of the opinion that the potential benefits of the palliative use of marijuana would likely outweigh the health risks of such use to the qualifying patient;

(5) Have prescribed, or have had a reasonable basis for determining that it is not in the best interest of the patient to prescribe, prescription drugs to address the symptoms or effects for which the written certification is being issued;

(6) Be reasonably available to provide follow-up care and treatment to the qualifying patient including, but not limited to, physical examinations, to determine the efficacy of marijuana for treating the qualifying patient’s debilitating medical condition or the symptom of the debilitating medical condition for which the written certification was issued;

(7) Comply with generally accepted standards of medical practice except to the extent

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such standards would counsel against certifying a qualifying patient for marijuana; and

(8) Explain the potential risks and benefits of the palliative use of marijuana to the qualifying patient and, if the qualifying patient lacks legal capacity, to a parent, guardian or person having legal custody of the qualifying patient, prior to submitting the written certification.

(c) A physician shall not delegate the responsibility of diagnosing a patient or determining whether a patient should be issued a written certification. Employees under the direct supervision of the physician may assist with preparing a written certification so long as the final written certification is reviewed and approved by the physician before it is submitted to the department.

(d) If a physician provides instructions for the use of marijuana to the patient, or includes instructions as part of the written certification, the physician shall also securely transmit such instructions to the qualifying patient's designated dispensary facility.

(Effective September 6, 2013)

Sec. 21a-408-3. Physician requirements for maintaining patient medical records

(a) A physician shall maintain medical records, as described in section 19a-14-40 of the Regulations of Connecticut State Agencies, for all patients for whom the physician has issued a written certification.

(b) A physician shall make a copy of such medical records reasonably available to the commissioner or the commissioner's authorized representative, to other state agencies and to state and local law enforcement agencies for the purpose of enabling the department or other agency to ensure compliance with the Act and sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies or for the purpose of investigating or prosecuting a violation of any provision of the Connecticut General Statutes or the Regulations of Connecticut State Agencies.

(Effective September 6, 2013)

Sec. 21a-408-4. Physician prohibitions

(a) A physician that has issued or intends to issue a written certification shall not:

(1) Directly or indirectly accept, solicit, or receive anything of value from a dispensary, dispensary facility backer, dispensary facility employee, producer, producer backer, production facility employee, provider of paraphernalia or any other person associated with a dispensary facility or production facility, except as permitted by section 21a-70e of the Connecticut General Statutes;

(2) Offer a discount or any other thing of value to a qualifying patient based on the patient's agreement or decision to use a particular primary caregiver, dispensary, dispensary facility or marijuana product;

(3) Examine a qualifying patient for purposes of diagnosing a debilitating medical condition at a location where marijuana or paraphernalia is acquired, distributed, dispensed, manufactured, sold, or produced; or

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(4) Directly or indirectly benefit from a patient obtaining a written certification. Such prohibition shall not prohibit a physician from charging an appropriate fee for the patient visit.

(b) A physician that issues written certifications, and such physician's co-worker, employee, spouse, parent or child, shall not have a direct or indirect financial interest in a dispensary, dispensary facility, producer, production facility, provider of paraphernalia, or any other entity that may benefit from a qualifying patient's or primary caregiver's acquisition, purchase or use of marijuana, including any formal or informal agreement whereby a producer, dispensary, or other person provides compensation if the physician issues a written certification for a qualifying patient or steers a qualifying patient to a specific dispensary facility, paraphernalia provider, or marijuana product.

(c) A physician shall not issue a written certification for such physician or for the physician's family members, employees or co-workers.

(d) A physician shall not provide product samples containing marijuana other than those approved by the federal Food and Drug Administration.

(Effective September 6, 2013)

Sec. 21a-408-5. Enforcement actions against physicians

(a) The commissioner may, after a hearing conducted pursuant to the Uniform Administrative Procedure Act, sections 4-166 to 4-189, inclusive, of the Connecticut General Statutes, issue an order to revoke or suspend a physician's controlled substance practitioner registration or to restrict a physician's controlled substance practitioner registration so as to prohibit the physician from issuing written certifications if the physician has:

(1) Failed to comply with any provision of the Act or sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies;

(2) Failed to comply with any provision of state statute or regulation concerning legend drugs or controlled substances; or

(3) Intentionally or negligently permitted another person to issue written certifications under the physician's name.

(b) If the commissioner has reason to believe that the public health, safety or welfare imperatively requires emergency action, the commissioner may issue an order restricting the physician's controlled substance practitioner registration to summarily prohibit the physician from issuing written certifications pending a hearing. Such hearing shall be conducted pursuant to the Uniform Administrative Procedure Act, sections 4-166 to 4-189, inclusive, of the Connecticut General Statutes.

(c) The commissioner may enter into an agreement with a physician placing conditions on the physician's controlled substance practitioner registration that prohibit or restrict the issuing of written certifications.

(d) In addition to any other action permitted in this section, the commissioner may refer any case involving an alleged violation by a physician of the Act or sections 21a-408-1 to

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21a-408-70, inclusive, of the Regulations of Connecticut State Agencies, to the Connecticut Medical Examining Board or to a Connecticut state or local law enforcement agency.

(Effective September 6, 2013)

Sec. 21a-408-6. Patient and primary caregiver registration

(a) A qualifying patient for whom a physician has issued a written certification, and the qualifying patient's primary caregiver where applicable, shall register with the department on forms, and in a manner, prescribed by the commissioner. For a registration application to be considered complete, the following items shall be submitted:

- (1) Written certification issued by a physician who meets the requirements set forth in the Act and section 21a-408-2 of the Regulations of Connecticut State Agencies;
- (2) Proof of residency of the qualifying patient acceptable to the department;
- (3) Proof of identity of the qualifying patient acceptable to the department;
- (4) Proof of the qualifying patient's age acceptable to the department;
- (5) A photograph of the qualifying patient meeting the following requirements:
 - (A) A current, digital, passport-size image, taken no more than thirty calendar days before the submission of the application;
 - (B) Taken against a plain white or off-white background or backdrop;
 - (C) At least two inches by two inches in size;
 - (D) In natural color;
 - (E) Provides a front, unobstructed view of the full face;
 - (F) Has between one and one and three-eighths inches from the bottom of the chin to the top of the head; and
 - (G) Is in "jpeg" format or such other format as the department may authorize;
- (6) A caregiver form, if applicable;
- (7) Proof of identity of the caregiver in a manner acceptable to the department;
- (8) Proof of the primary caregiver's age acceptable to the department;
- (9) A photograph of the caregiver meeting the requirements set forth in subsection (a)(5) of this section;
- (10) Permission for the department to determine whether the patient is an inmate confined in a correctional institution or facility under the supervision of the Department of Correction;
- (11) Permission for the department to conduct a background check of the primary caregiver for the purpose of determining if such applicant has been convicted of a violation of any law pertaining to the illegal manufacture, sale or distribution of a controlled substance;
- (12) Payment of the appropriate fees as set forth in section 21a-408-28 of the Regulations of Connecticut State Agencies;
- (13) The name, address and telephone number of the dispensary facility from which the qualifying patient or the patient's primary caregiver will purchase marijuana; and
- (14) Such other information as the department may reasonably require to determine the

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applicant's suitability for registration or to protect public health and safety.

(b) If a registration application is determined to be inaccurate or incomplete, the department shall send the applicant a notice of deficiency. If the applicant corrects the deficiencies sixty days or less after receiving notice from the department, the department shall not charge any additional fees.

(c) The department shall deny an application if an applicant submits corrections or supplies the missing information more than sixty days after receiving a notice of deficiency from the department, or if the applicant fails to provide correct and complete information on their second attempt. Any such applicant may resubmit the registration application materials with all applicable fees for a new registration.

(d) A qualifying patient shall only designate, and the department shall only register, one primary caregiver for the patient at any given time.

(e) Absent permission from the commissioner for good cause shown, a qualifying patient may only change primary caregivers once per year at the time of renewal. A qualifying patient may change primary caregivers at the time of their registration renewal by requesting a different primary caregiver, who shall meet the requirements of the Act and this section, and be approved by the commissioner prior to the patient's registration certificate being renewed. If the qualifying patient requests permission to change primary caregiver prior to renewal, the qualifying patient shall submit a change of caregiver request form to the department, which shall set forth the reasons the qualifying patient seeks to change primary caregivers. If the department approves such change of primary caregiver request, the new primary caregiver shall register with the department and shall submit the non-refundable primary caregiver application fee required by section 21a-408-28 of the Regulations of Connecticut State Agencies. The department shall approve a new primary caregiver only if such person meets the requirements of the Act and this section.

(f) A qualifying patient who lacked legal capacity at the time of the most recent application or renewal may not change primary caregivers unless:

(1) The qualifying patient provides a court order, or other proof acceptable to the department, indicating that the qualifying patient no longer lacks legal capacity, in which case the qualifying patient may change caregivers in accordance with subsection (e) of this section; or

(2) The primary caregiver is no longer willing or able to serve as a caregiver, in which case the qualifying patient's new primary caregiver applicant shall:

(A) Certify to the department that the current primary caregiver can no longer serve or no longer wishes to serve as a caregiver; and

(B) Submit an application and registration fee that meets the requirements of the Act and this section .

(Effective September 6, 2013)

Sec. 21a-408-7. Denial of a qualifying patient or primary caregiver registration application

(a) The department may deny an application or renewal of a qualifying patient's registration certificate if the applicant:

(1) Does not meet the requirements set forth in the Act or section 21a-408-6 of the Regulations of Connecticut State Agencies;

(2) Fails to properly complete the application form;

(3) Does not provide acceptable proof of identity, residency or age to the department;

(4) Provides false, misleading or incorrect information to the department;

(5) Fails to provide a photograph in accordance with section 21a-408-6(a)(5) of the Regulations of Connecticut State Agencies;

(6) Has had a qualifying patient's registration denied, suspended or revoked by the department in the previous six months;

(7) Has not paid all applicable fees as required by section 21a-408-28 of the Regulations of Connecticut State Agencies;

(8) Has a written certification issued by a physician who is not authorized to certify patients for marijuana; or

(9) Needs a primary caregiver according to the written certification issued by the physician and:

(A) The applicant has not designated a primary caregiver; or

(B) The department has denied the application of the primary caregiver designated by the qualifying patient.

(b) The department may deny an application or the renewal of a primary caregiver's registration certificate if the qualifying patient's physician has not certified the need for the patient to have a primary caregiver or if the primary caregiver applicant:

(1) Does not meet the qualifications set forth in the Act or section 21a-408-6 of the Regulations of Connecticut State Agencies;

(2) Has a disqualifying conviction;

(3) Fails to properly complete the primary caregiver application form;

(4) Does not provide acceptable proof of identity or age to the department;

(5) Fails to provide a photograph in accordance with section 21a-408-6(a)(5) of the Regulations of Connecticut State Agencies;

(6) Has not paid all applicable fees as required by section 21a-408-28 of the Regulations of Connecticut State Agencies;

(7) Provides false, misleading or incorrect information to the department;

(8) Has had a primary caregiver registration denied, suspended or revoked in the previous six months;

(9) Is already a primary caregiver, or has already applied to be a primary caregiver, for a different qualifying patient, unless the primary caregiver provides proof acceptable to the department demonstrating that the primary caregiver has a parental, guardianship, conservatorship or sibling relationship with each qualifying patient; or

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(10) Is designated as a primary caregiver for a qualifying patient whose application is denied by the department or whose qualifying patient registration certificate has been suspended or revoked.

(c) If the commissioner denies an application or renewal of a qualifying patient applicant or primary caregiver applicant, the commissioner shall provide the applicant with notice of the grounds for the denial and shall inform the applicant of the right to request a hearing.

(1) Upon receipt of such notice, the applicant may request a hearing, which request shall be submitted to the department in writing not more than twenty calendar days after the date of the notice.

(2) If the applicant makes a timely request for a hearing, the commissioner shall conduct a hearing in accordance with the Uniform Administrative Procedure Act, sections 4-166 to 4-189, inclusive, of the Connecticut General Statutes.

(3) If the applicant does not request a hearing in writing in a timely manner, the applicant shall be deemed to have waived the right to a hearing.

(Effective September 6, 2013)

Sec. 21a-408-8. Revocation or suspension of a qualifying patient or primary caregiver registration

(a) The commissioner may revoke or suspend the registration certificate of a qualifying patient, in accordance with the Uniform Administrative Procedure Act, sections 4-166 to 4-189, inclusive, of the Connecticut General Statutes, under the following circumstances:

(1) The qualifying patient becomes an inmate confined in a correctional institution or facility under the supervision of the Department of Correction;

(2) The qualifying patient's physician notifies the department that the physician is withdrawing the written certification submitted on behalf of the qualifying patient and, thirty days after the physician's withdrawal of the written certification, the patient has not obtained a valid written certification from a different physician;

(3) The qualifying patient or primary caregiver provided false, misleading or incorrect information to the department;

(4) The qualifying patient is no longer a resident of Connecticut;

(5) The qualifying patient, together with the qualifying patient's caregiver where applicable, obtains more than a one-month supply of marijuana in a one-month period;

(6) The qualifying patient provides or sells marijuana to any person, including another registered qualifying patient or primary caregiver;

(7) The qualifying patient uses marijuana in a place or manner not permitted by the Act or sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies;

(8) The qualifying patient uses marijuana in a manner that puts others at risk or fails to take reasonable precautions to avoid putting others at risk;

(9) The qualifying patient permits another person to use the qualifying patient's registration certificate;

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(10) The qualifying patient tampers, falsifies, alters, modifies or allows another person to tamper, falsify, alter or modify, the qualifying patient's registration certificate;

(11) The qualifying patient's physician is no longer available to provide care to the patient and, after thirty days from the physician notifying the department of the physician's unavailability, the patient has not established a bona-fide relationship with a different physician;

(12) The primary caregiver notifies the department that the primary caregiver is no longer willing to serve as a primary caregiver for the qualifying patient, or the primary caregiver's registration certification has been suspended or revoked, in which case the qualifying patient shall have thirty days to register an acceptable primary caregiver with the department before the department may commence an action to suspend or revoke the qualifying patient's registration;

(13) The qualifying patient's registration certificate is lost, stolen or destroyed and the patient or the patient's primary caregiver fails to notify the department or notifies the department of such incident more than five business days after becoming aware that the registration certificate was lost, stolen or destroyed;

(14) The qualifying patient fails to notify the department of a change in registration information or notifies the department of such change more than five business days after the change; or

(15) The qualifying patient has violated any section of the Act or sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies.

(b) The department may revoke or suspend the registration certificate of a primary caregiver, in accordance with the Uniform Administrative Procedures Act, sections 4-166 to 4-189, inclusive, of the Connecticut General Statutes, under the following circumstances:

(1) The registration certification of the qualifying patient has been revoked or suspended;

(2) The qualifying patient's physician notifies the department that the qualifying patient is no longer in need of a primary caregiver;

(3) The qualifying patient or primary caregiver provided false, misleading or incorrect information to the department;

(4) The qualifying patient registers a different person to serve as the primary caregiver in accordance with the procedure set forth in section 21a-408-6 of the Regulations of Connecticut State Agencies;

(5) The primary caregiver obtains more than a one-month supply of marijuana in a one-month period on behalf of a single qualifying patient;

(6) The primary caregiver obtains marijuana for, or provides or sells marijuana to, any person other than the qualifying patient of the primary caregiver, including a different qualifying patient or primary caregiver;

(7) The primary caregiver permits another person to use the primary caregiver's registration certificate;

(8) The primary caregiver has tampered, altered, modified, falsified, or allowed any person to tamper, alter, modify or falsify, the primary caregiver's registration certificate or

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the registration certificate of the qualifying patient;

(9) The primary caregiver has permitted the use of marijuana that endangers the health or well-being of a person other than the qualifying patient or primary caregiver;

(10) The primary caregiver has a disqualifying conviction;

(11) The primary caregiver's registration certificate is lost, stolen or destroyed and the primary caregiver fails to notify the department or notifies the department of such incident more than five business days after becoming aware that the registration certificate was lost, stolen or destroyed;

(12) The primary caregiver fails to notify the department of a change in registration information or notifies the department of such change more than five business days after the change; or

(13) The primary caregiver has violated any section of the Act or sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies.

(Effective September 6, 2013)

Sec. 21a-408-9. Reporting requirements for physicians, patients and caregivers

(a) A physician shall report to the department, in a manner prescribed by the commissioner, the death of a qualifying patient or change in status of a debilitating medical condition involving a qualifying patient for whom the physician has issued a written certification if such change may affect the patient's continued eligibility to use marijuana. A physician shall report such death or change of status not more than five business days after the physician becomes aware of such fact.

(b) A qualifying patient or primary caregiver, who has been issued a registration certificate, shall notify the department of any change in the information provided to the department not later than five business days after such change. A qualifying patient or primary caregiver shall report changes that include, but are not limited to, a change in the qualifying patient's name, address, contact information, medical status, or status with the Department of Corrections. A qualifying patient or primary caregiver shall report such changes on a form, and in a manner, prescribed by the commissioner.

(c) A qualifying patient or primary caregiver may change the patient's designated dispensary facility no more than four times per year without good cause shown and prior approval by the commissioner or the commissioner's authorized representative. A qualifying patient or primary caregiver shall report the change on a form and in a manner prescribed by the commissioner. A change in the designated dispensary facility shall not be effective until five business days after the qualifying patient or primary caregiver notifies the department of such change. A qualifying patient or primary caregiver shall only purchase marijuana from the dispensary facility currently designated by the patient or caregiver with the department.

(d) If a qualifying patient's or primary caregiver's appearance has substantially changed such that the photograph submitted to the department does not accurately resemble such qualifying patient or primary caregiver, such person shall submit, in a timely manner, an

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updated photograph that meets the requirements set forth in section 21a-408-6(a)(5) of the Regulations of Connecticut State Agencies.

(e) If a qualifying patient has a primary caregiver, that primary caregiver may notify the department of any changes on behalf of the qualifying patient using the same forms and process prescribed for qualifying patients.

(f) If a qualifying patient or primary caregiver notifies the department of any change that results in information on the registration certificate being inaccurate or the photograph needing to be replaced, the qualifying patient or primary caregiver shall submit the fee required by section 21a-408-28 of the Regulations of Connecticut State Agencies for a replacement registration certificate. The department shall thereafter issue the qualifying patient or primary caregiver a new registration certificate provided the applicant continues to satisfy the requirements of the Act and sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies. Upon receipt of a new registration certificate, the qualifying patient or primary caregiver shall destroy in a non-recoverable manner the registration certificate that was replaced.

(g) If a qualifying patient or primary caregiver becomes aware of the loss, theft or destruction of the registration certificate of such qualifying patient or primary caregiver, the qualifying patient or primary caregiver shall notify the department, on a form and in a manner prescribed by the commissioner, not later than five business days of becoming aware of the loss, theft or destruction, and submit the fee required by section 21a-408-28 of the Regulations of Connecticut State Agencies for a replacement registration certificate. The department shall inactivate the initial registration certificate upon receiving such notice and issue a replacement registration certificate upon receiving the applicable fee provided the applicant continues to satisfy the requirements of the Act and sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies.

(Effective September 6, 2013)

Sec. 21a-408-10. Precautions for preventing the loss, theft or misuse of marijuana by patients and caregivers

(a) A qualifying patient and primary caregiver shall store marijuana in a secure location to prevent theft, loss or access by unauthorized persons.

(b) Qualifying patients and primary caregivers shall carry their registration certificate with them whenever they are in possession of marijuana.

(Effective September 6, 2013)

Sec. 21a-408-11. Proper disposal of marijuana by patients or caregivers

A patient or caregiver shall dispose of all usable marijuana in the patient's or caregiver's possession no later than ten calendar days after the expiration of the patient's registration certificate, if such certificate is not renewed, or sooner should the patient no longer wish to possess marijuana for palliative use. A patient or caregiver shall complete such disposal by one of the following methods:

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(1) By rendering the marijuana non-recoverable in accordance with the department's proper disposal instructions, which are available on the department's Internet web site at www.ct.gov/dcp/drugdisposal;

(2) By depositing it in a Connecticut police department medication drop-box; or

(3) By disposing of the marijuana at a government-recognized drug take-back program located in Connecticut.

(Effective September 6, 2013)

Sec. 21a-408-12. Establishment of additional debilitating medical conditions, medical treatments or diseases

(a) The commissioner shall not add a medical condition, medical treatment or disease to the list of debilitating medical conditions under the Act unless the appropriateness of adding the condition, treatment or disease has been considered by the board, the board has submitted a written recommendation to the commissioner in accordance with this section and the commissioner has adopted a regulation in accordance with subsection (k) of this section.

(b) Persons seeking to add a medical condition, medical treatment or disease to the list of debilitating medical conditions under the Act shall submit a written petition to the commissioner and request that the commissioner present the petition to the board.

(c) Absent a showing of good cause, the commissioner shall only present a petition to the board if it includes the following information:

(1) The extent to which the medical condition, medical treatment or disease is generally accepted by the medical community and other experts as a valid, existing medical condition, medical treatment or disease;

(2) If one or more treatments for the condition, rather than the condition itself, are alleged to be the cause of a patient's suffering, the extent to which the treatments causing suffering are generally accepted by the medical community and other experts as valid treatments for the condition;

(3) The extent to which the condition or the treatments thereof cause severe or chronic pain, severe nausea, spasticity or otherwise substantially limits one or more major life activities of the patient;

(4) The availability of conventional medical therapies, other than those that cause suffering, to alleviate suffering caused by the condition or the treatment thereof;

(5) The extent to which evidence that is generally accepted among the medical community and other experts supports a finding that the use of marijuana alleviates suffering caused by the condition or the treatment thereof;

(6) Any information or studies known to the petitioner regarding any beneficial or adverse effects from the use of marijuana in patients with the medical condition, medical treatment or disease that is the subject of the petition; and

(7) Letters of support from physicians or other licensed health care professionals knowledgeable about the condition, treatment or disease.

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(d) If a medical condition, medical treatment or disease in a petition has been previously considered and rejected by the commissioner, or is determined by the commissioner to be substantially similar to such a rejected condition, treatment or disease, the commissioner may deny the petition without first submitting it to the board unless new scientific research supporting the request is included in the petition.

(e) If a written petition meets the requirements of this section, the commissioner shall refer the written petition to the board for a public hearing at the next board meeting that is at least sixty days after the date the petition was submitted and at which the board will be considering petitions.

(f) At least twice per year, the board shall conduct a public hearing to evaluate any petitions referred to it by the commissioner and to consider any other medical conditions, medical treatments or diseases that the board, on its own initiative, believes should be reviewed for possible inclusion on the list of debilitating medical conditions under the Act.

(g) No less than twenty days before each public hearing at which the board will consider petitions or the inclusion of debilitating conditions on its own initiative, the department shall publish on its Internet web site a list of the debilitating medical conditions, medical treatments and diseases that the board will be considering at its upcoming hearing so that the petitioner, where applicable, and other members of the public may offer public comments before the board.

(h) In addition to information provided in a petition, the board may examine scientific, medical or other evidence and research pertaining to the petition, and may gather information, in person or in writing, from other persons knowledgeable about the medical condition, medical treatment or disease being considered.

(i) Following the public hearing, the board shall consider the public comments and any additional information or expertise made available to the board for each proposed debilitating medical condition considered at the hearing. The board shall issue a written recommendation to the commissioner as to whether the medical condition, medical treatment or disease should be added to the list of debilitating medical conditions that qualify for the palliative use of marijuana. The board shall include in its recommendation the following:

- (1) Whether the medical condition, medical treatment or disease is debilitating;
- (2) Whether marijuana is more likely than not to have the potential to be beneficial to treat or alleviate the debilitation associated with the medical condition, medical treatment or disease; and
- (3) Other matters that the board considers relevant to the approval or the denial of the petition.

(j) At least three members of the board, which shall constitute a quorum, shall consider each proposed debilitating medical condition. A majority of the board members present at the hearing where each proposed debilitating medical condition was presented for public comment shall concur in the recommendation submitted to the commissioner and that recommendation shall be considered the official recommendation of the board. Any board

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member who disagrees with the board's official recommendation may submit a dissenting or concurring recommendation to the commissioner.

(k) If, after receiving the board's official recommendation and any dissenting or concurring recommendation, the commissioner concludes that the medical condition, medical treatment or disease that was under consideration should be added to the list of debilitating medical conditions under the Act, the commissioner shall proceed to adopt regulations, in accordance with section 21a-408m of the Connecticut General Statutes and the Uniform Administrative Procedures Act, sections 4-166 to 4-189, inclusive, of the Connecticut General Statutes, expanding the list of debilitating medical conditions accordingly.

(Effective September 6, 2013)

Sec. 21a-408-12a. Additional Debilitating Medical Conditions

In accordance with the procedures set forth in section 21a-408a-12 of the Regulations of Connecticut State Agencies, the following medical conditions, medical treatments or diseases shall be added to the list of debilitating medical conditions:

- (1) Sickle cell disease;
- (2) Post laminectomy syndrome with chronic radiculopathy;
- (3) Severe psoriasis and psoriatic arthritis;
- (4) Amyotrophic lateral sclerosis;
- (5) Ulcerative colitis; and
- (6) Complex regional pain syndrome, Type 1 and Type II.

(Effective March 4, 2016)

Sec. 21a-408-13. Number of dispensaries and dispensary facilities

(a) Only a dispensary at a dispensary department may dispense marijuana.

(b) The commissioner shall issue at least one dispensary facility license and may issue additional dispensary facility licenses upon a determination that additional dispensary facilities are desirable to assure access to marijuana for qualifying patients. Such determination shall be made based on the size and location of the dispensary facilities in operation, the number of qualifying patients registered with the department and the convenience and economic benefits to qualifying patients.

(c) Each dispensary facility may employ no more than five dispensaries at a time without prior approval from the commissioner, one of whom shall be designated as the dispensary facility manager.

(Effective September 6, 2013)

Sec. 21a-408-14. Dispensary facility license selection

(a) The department shall publish on its Internet web site, and in such other places as the department deems appropriate, a notice of open applications for dispensary facility licenses. Such notice shall include, but not be limited to:

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- (1) The maximum number of licenses to be awarded;
- (2) Information on how to obtain an application;
- (3) The deadline for receipt of applications;
- (4) Acceptable methods for submitting an application;
- (5) The preferred locations, if any, for the dispensary facility licenses; and
- (6) The criteria that shall be considered in awarding the dispensary facility licenses.

(b) Following the deadline for receipt of applications, the commissioner shall evaluate each complete and timely submitted application and award dispensary facility licenses on a competitive basis based on the criteria set out in the notice for applications. In the event the commissioner determines that there are an insufficient number of qualified applicants to award all of the dispensary facility licenses that the commissioner has determined are desirable, the department may republish, in accordance with this section, a notice of open applications for dispensary facility licenses.

(c) The commissioner shall consider, but is not limited to, the following criteria in evaluating dispensary facility license applications:

(1) The character and fitness of the dispensary, dispensary facility backers and any other person who may have control or influence over the operation of the proposed dispensary facility;

(2) The location for the proposed dispensary facility including, but not limited to:

(A) Its proximity to previously approved dispensary facilities or pending dispensary facility applications;

(B) Whether the registered patient population in the area proposed by the dispensary facility applicant justifies the need for a dispensary facility, or an additional dispensary facility, in that area;

(C) Whether the proximity of the proposed dispensary facility will have a detrimental effect upon any place used primarily for religious worship, public or private school, convent, charitable institution, whether supported by private or public funds, hospital or veterans' home or any camp or military establishment;

(D) Whether the number of dispensary facilities in the locality is such that the granting of a license is detrimental to the public interest. In reaching a conclusion in this respect, the commissioner may consider the population of, the number of like licenses and number of all licenses existent in, the particular town and the immediate neighborhood concerned, the effect that a new license may have on such town or neighborhood or on like licenses existent in such town or neighborhood;

(3) The applicant's ability to maintain adequate control against the diversion, theft and loss of marijuana;

(4) The applicant's ability to maintain the knowledge, understanding, judgment, procedures, security controls and ethics to ensure optimal safety and accuracy in the dispensing and sale of marijuana; and

(5) The extent to which the applicant or any of the applicant's dispensary facility backers have a financial interest in another licensee, registrant or applicant under the Act or sections

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21a-408-1 to 21a-408-70 of the Regulations of Connecticut State Agencies.

(6) Any other reason provided by Connecticut state or federal statute or Connecticut state or federal regulation that is not inconsistent with the Act or sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies and that warrants consideration.

(d) The commissioner shall have the right to amend the notice of open applications prior to the deadline for submitting an application. Such amended notice shall be published in the same manner as the original notice of open applications.

(e) The commissioner shall have the right to cancel a notice of open applications prior to the award of a dispensary facility license.

(f) The commissioner may disqualify any applicant who:

(1) Submits an incomplete, false, inaccurate or misleading application;

(2) Fails to submit an application by the published deadline; or

(3) Fails to pay all applicable fees;

(g) The decision of the commissioner not to award a dispensary facility license to an applicant shall be final.

(h) If an applicant has been awarded a dispensary facility license and has not commenced operation of such facility within one hundred twenty days of being notified of the dispensary facility license award, the commissioner may, in the commissioner's discretion, rescind such dispensary facility license, unless such delay was caused by a *force majeure*. A dispensary facility shall be deemed to have commenced operation if the dispensary facility is capable of operating in accordance with the dispensary facility applicant's approved application. In the event a dispensary facility license is rescinded pursuant to this subsection, the commissioner shall award a dispensary facility license by selecting among the qualified applicants who applied for the dispensary facility license subject to rescission. If no other qualified applicant applied for such dispensary facility license or satisfied the criteria for awarding a license, the department shall publish, in accordance with this section, a notice of open applications for dispensary facility licenses.

(Effective September 6, 2013)

Sec. 21a-408-15. Dispensary facility license applications

(a) Only a dispensary facility that has obtained a license from the department may sell marijuana to qualified patients and primary caregivers that have a registration certificate from the department.

(b) A dispensary facility license applicant shall submit an application form and the fees required by section 21a-408-28 of the Regulations of Connecticut State Agencies, as well as all other required documentation on forms prescribed by the commissioner.

(c) The applicant shall provide the following information and records in the application process:

(1) The name and address of the applicant, the applicant's dispensary facility backers, if any, and the person who will serve as the dispensary facility manager if the application is

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approved;

(2) The location for the dispensary facility that is to be operated under such license;

(3) A financial statement setting forth all elements and details of any business transactions connected with the application;

(4) A detailed description of any other services or products to be offered by the dispensary facility;

(5) Details regarding the applicant's plans to maintain adequate control against the diversion, theft or loss of marijuana;

(6) Details of any felony conviction or of any criminal conviction related to controlled substances or legend drugs of the applicant or applicant's backers;

(7) Documents sufficient to establish that the applicant is authorized to conduct business in Connecticut and that all applicable state and local building, fire and zoning requirements and local ordinances will be met;

(8) Permission for the department to conduct a background check on the applicant and the applicant's backers, if any, for the purpose of determining if such applicant and applicant's backers are suitable to own and operate a dispensary facility;

(9) Any business and marketing plans related to the operation of the dispensary facility or the sale of marijuana;

(10) Text and graphic materials showing the exterior appearance of the proposed dispensary facility and its site compatibility with commercial or residential structures already constructed or under construction within the immediate neighborhood;

(11) A blueprint of the proposed dispensary facility, which shall, at a minimum, show and identify:

(A) The square footage of the area which will constitute the dispensary department;

(B) The square footage of the overall dispensary facility;

(C) The square footage and location of areas used as storerooms or stockrooms;

(D) The size of the counter that will be used for selling marijuana;

(E) The location of the dispensary facility sink and refrigerator, if any;

(F) The location of all approved safes and approved vaults that will be used to store marijuana;

(G) The location of the toilet facilities;

(H) The location of a break room and location of personal belonging lockers;

(I) The location and size of patient counseling areas, if any;

(J) The locations where any other products or services will be offered; and

(K) The location of all areas that may contain marijuana showing the location of walls, partitions, counters and all areas of ingress and egress;

(12) Documents related to any compassionate need program the dispensary facility intends to offer; and

(13) Such other documents and information reasonably required by the department to determine the applicant's suitability for registration or to protect public health and safety.

(d) In the event any information contained in the application or accompanying documents

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changes after being submitted to the department, the applicant shall immediately notify the department in writing and provide corrected information in a timely manner so as not to disrupt the license selection process.

(e) The department may verify information contained in each application and accompanying documentation in order to assess the applicant's character and fitness to operate a dispensary facility. The department may verify the information and assess the applicant's character and fitness by, among other things:

(1) Contacting the applicant by telephone, mail, electronic mail or such other means as are reasonable under the circumstances;

(2) Conducting an on-site visit of the proposed dispensary facility location or other dispensary facility locations associated with the applicant or the applicant's dispensary facility backers;

(3) Conducting background checks or contacting references of the applicant, the applicant's dispensary facility backers and the dispensary facility backers' members, shareholders or investors;

(4) Contacting state regulators in any other states where the applicant, the applicant's dispensary facility backers and the dispensary facility backers' members, shareholders or investors are engaged in, or have sought to be engaged in, any aspect of that state's medical marijuana program; and

(5) Requiring a personal meeting with the applicant and the submission of additional information or documents.

(Effective September 6, 2013)

Sec. 21a-408-16. Dispensary facility employee licenses and registrations

(a) No person shall act as a dispensary without a license issued by the department under the Act and section 21a-408-24 of the Regulations of Connecticut State Agencies.

(b) No person shall act as a dispensary technician without being registered with the department under the Act and section 21a-408-24 of the Regulations of Connecticut State Agencies.

(c) No person shall be employed or retained as any other type of dispensary facility employee without being at least 18 years of age and being registered by the department under the Act and section 21a-408-24 of the Regulations of Connecticut State Agencies.

(d) Any dispensary facility backer, or other person who will exercise control over, or have management responsibility for, a dispensary facility shall be registered with the department pursuant to section 21a-408-24 of the Regulations of Connecticut State Agencies.

(e) Only a pharmacist who is in good standing and has an active pharmacist license issued by the department may apply for and receive a dispensary license.

(f) Only a person who has held an active pharmacy technician registration in Connecticut within the five years prior to the application, who is 18 years of age or older, and is currently in good standing, or was in good standing at the time his or her registration lapsed, may

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apply for and receive a dispensary technician registration.

(Effective September 6, 2013)

Sec. 21a-408-17. Notification of changes by dispensary facility

(a) Unless otherwise provided in sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies, the dispensary facility manager shall provide any notification or information that is required from a dispensary facility pursuant to sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies, except that if the notification or information relates to a change in the dispensary facility manager, or if the dispensary facility manager is otherwise not available to provide the notification or information to the department, a dispensary facility backer shall provide such notification or information.

(b) Prior to any person becoming affiliated with a dispensary facility, including any change associated with a change in ownership, such person shall comply with the licensing and registration requirements set forth in section 21a-408-16 of the Regulations of Connecticut State Agencies. No person shall commence such affiliation until approved by the commissioner.

(c) Prior to making any change to the dispensary facility name, the dispensary facility shall submit an application, on a form prescribed by the commissioner, for such change to the department and pay the fee set forth in section 21a-408-28 of the Regulations of Connecticut State Agencies. No dispensary facility shall make such change until approved by the commissioner.

(d) Prior to changing a dispensary facility location, the dispensary facility shall submit an application, on a form prescribed by the commissioner, for such change to the department and pay the fee set forth in section 21a-408-28 of the Regulations of Connecticut State Agencies. No dispensary facility shall make such change until approved by the commissioner.

(e) Prior to any modification, remodeling, expansion, reduction or other physical, non-cosmetic alteration of a dispensary facility or a dispensary department, the dispensary facility shall submit an application, on a form prescribed by the commissioner, for such change to the department and pay the fee set forth in section 21a-408-28 of the Regulations of Connecticut State Agencies. No dispensary facility shall make such change until approved by the commissioner.

(f) Prior to designating a new dispensary facility manager, the dispensary facility shall submit a change of dispensary facility manager form to the department and pay the fee set forth in section 21a-408-28 of the Regulations of Connecticut State Agencies. No dispensary facility shall make such change in dispensary facility manager until approved by the commissioner. In the event of an emergency such that the designated dispensary facility manager is no longer able or willing to continue managing the dispensary department, the dispensary facility backer or current dispensary facility manager shall immediately notify the department that the dispensary facility manager has ceased such management and shall

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immediately notify the department of the name, address and dispensary license number of the dispensary who assumes management of the dispensary facility. Such person shall serve as the acting dispensary facility manager until such time as the commissioner approves a new dispensary facility manager. The dispensary facility shall submit a change of dispensary facility manager form and accompanying fee to the department to designate a permanent dispensary facility manager not more than fifteen business days after the previously designated dispensary facility manager has ceased management responsibilities.

(g) The dispensary facility shall notify the department no later than ten business days after the date that a dispensary facility backer or dispensary facility employee ceases to work for, or be affiliated with, the dispensary facility.

(h) If a dispensary facility will be closing, the dispensary facility manager for the facility shall notify the department of the closing not less than fifteen days prior to the closing.

(Effective September 6, 2013)

Sec. 21a-408-18. Notification of changes by dispensary and dispensary technician

(a) Every dispensary and dispensary technician whose place of employment changes shall report to the department the following information regarding the dispensary or dispensary technician's new employment. Such notification shall be made, on a form prescribed by the commissioner, no less than five business days after the change in employment becomes effective.

(b) Any dispensary or dispensary technician whose name or home address changes shall notify the department of such change, on a form prescribed by the commissioner, no less than five business days after the change.

(Effective September 6, 2013)

Sec. 21a-408-19. Number of producers

(a) The department shall issue at least three, but no more than ten, producer licenses.

(b) Prior to issuing any additional producer licenses, the commissioner shall determine that additional producers are desirable to assure access to marijuana for qualifying patients, which determination shall be made based on the size and location of the production facilities in operation, the amount of marijuana each production facility is producing, the number of qualifying patients registered with the department and the convenience and economic benefits to qualifying patients or dispensary facilities.

(Effective September 6, 2013)

Sec. 21a-408-20. Producer selection

(a) The department shall publish on its Internet web site, and in such other places as the department deems appropriate, a notice of open applications for producer licenses. Such notice shall include, but not be limited to:

- (1) The maximum number of producer licenses to be awarded;
- (2) Information on how to obtain an application;

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- (3) The deadline for receipt of applications;
- (4) Acceptable methods for submitting an application; and
- (5) The criteria that shall be considered in awarding the producer license.

(b) Following the deadline for receipt of applications, the department shall evaluate each complete and timely submitted application and award producer licenses on a competitive basis based on the criteria set out in the notice for applications. In the event the commissioner determines that there are an insufficient number of qualified applicants to award all of the producer licenses that the commissioner has determined are desirable, the department may republish, in accordance with this section, a notice of open applications for producer licenses.

(c) The department shall consider, but is not limited to, the following criteria in evaluating producer license applications:

(1) The location for the proposed production facility to be owned or leased and operated by the producer including, but not limited to:

(A) Whether the proximity of the proposed production facility will have a detrimental effect upon any place used primarily for religious worship, public or private school, convent, charitable institution, whether supported by private or public funds, hospital or veterans' home or any camp or military establishment;

(B) Whether the number of production facilities in the locality is such that the granting of an additional license is detrimental to the public interest. In reaching a conclusion in this respect, the commissioner may consider the population of, the number of like licenses and number of all licenses existent in, the particular town and the immediate neighborhood concerned and the effect that a new license may have on such town or neighborhood or on like licenses existent in such town or neighborhood; and

(C) If the production facility is leased, whether the lease agreement limits access to the facility by the owner of the facility, or a representative or agent of the owner, except on conditions permitted by the Act and section 21a-408-53 of the Regulations of Connecticut State Agencies;

(2) The character and fitness of the producer, producer backers, and any other person who may have control or influence over the producer or production facility;

(3) Detailed information regarding the applicant's financial position, indicating all assets, liabilities, income and net worth, to demonstrate the financial capacity of the applicant to build and operate a production facility;

(4) The applicant's ability to maintain adequate control against the diversion, theft and loss of marijuana produced or manufactured at the production facility;

(5) The applicant's ability to produce pharmaceutical grade marijuana for palliative use in a secure, indoor facility;

(6) The applicant's expertise in agriculture and other production techniques required to produce pharmaceutical grade marijuana or to manufacture marijuana products;

(7) Proof acceptable to the commissioner that the applicant can establish and maintain an escrow account in a financial institution in Connecticut, a letter of credit drawn from a

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financial institution in Connecticut or a surety bond issued by a surety company licensed by the state of Connecticut Department of Insurance and of a capacity and rating acceptable to the commissioner, in the secured amount of two million dollars. Any escrow account agreement, letter of credit or surety bond shall adhere to the terms and conditions set forth by the commissioner in the request for applications. The establishment of such escrow account, letter of credit or surety bond shall be required prior to issuance of a producer license;

(8) The extent to which the applicant or any of the applicant's producer backers have a financial interest in another licensee, registrant or applicant under the Act or sections 21a-408-1 to 21a-408-70 of the Regulations of Connecticut State Agencies; and

(9) Any other factors provided by Connecticut state or federal statute or Connecticut or federal regulation that are not inconsistent with the Act or sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies and that warrant consideration.

(d) The commissioner shall have the right to amend the notice of open applications prior to the deadline for submitting an application. The commissioner shall publish such amended notice in the same manner as the original notice of open applications.

(e) The commissioner shall have the right to cancel a notice of open applications prior to the award of a producer license.

(f) The commissioner may disqualify any applicant who:

- (1) Submits an incomplete, false, inaccurate or misleading application;
- (2) Fails to submit an application by the published deadline; or
- (3) Fails to pay all applicable fees.

(g) The decision of the commissioner not to award a producer license to an applicant shall be final.

(h) If an applicant has been awarded a producer license and has not commenced operation of a production facility within 180 days of being notified of the producer license award, the commissioner may, in the commissioner's discretion, rescind such producer license unless such delay was caused by *force majeure*. A producer shall be deemed to have commenced operation if the production facility is fully constructed and capable of operating in accordance with the producer's approved application. In the event a producer license is rescinded pursuant to this subsection, the commissioner shall award a producer license by selecting among the qualified applicants who applied for the producer license subject to rescission. If no other qualified applicant applied for such producer license or satisfied the criteria for awarding a license, the department shall publish, in accordance with this section, a notice of open applications for producer license.

(Effective September 6, 2013)

Sec. 21a-408-21. Producer applications

(a) A producer shall submit an application form and the fees required by section 21a-408-28 of the Regulations of Connecticut State Agencies, as well as all other required

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documentation on forms prescribed by the commissioner.

(b) The applicant shall provide the following information in the application process and maintain the following records, as applicable:

- (1) The name and address of the applicant and the applicant's producer backers, if any;
- (2) The location for the production facility that is to be operated under such producer license;
- (3) A financial statement setting forth all elements and details of any business transactions connected with the application;
- (4) Details of any felony conviction or of any criminal conviction related to controlled substances or legend drugs of the applicant or applicant's backers;
- (5) Details regarding the applicant's plans to maintain adequate control against the diversion, theft or loss of marijuana;
- (6) Documents sufficient to establish that the applicant is authorized to conduct business in Connecticut and that all applicable state and local building, fire and zoning requirements and local ordinances will be met; with regard to zoning, it shall be sufficient to establish that the proposed location is in a zone where a pharmaceutical manufacturing facility would be allowed;
- (7) Permission for the department to conduct a background check on the applicant and the applicant's backers, if any for the purpose of determining if such applicant and applicant's backers are suitable to own and operate a producer or production facility;
- (8) Any proposed business and marketing plans, including expected production capacity;
- (9) Text and graphic materials showing the exterior appearance of the proposed production facility and its site compatibility with commercial or residential structures already constructed or under construction within the immediate neighborhood;
- (10) A blueprint of the proposed production facility to be operated by the licensee, which shall, at a minimum, show and identify:
 - (A) The square footage of the areas where marijuana is to be grown;
 - (B) The square footage of the areas where marijuana is to be harvested;
 - (C) The square footage of the areas where marijuana is to be packaged and labeled;
 - (D) The square footage of the areas where marijuana is to be produced and manufactured;
 - (E) The square footage of the overall production facility;
 - (F) The square footage and location of areas to be used as storerooms or stockrooms;
 - (G) The location of any approved safes or approved vaults that are to be used to store marijuana;
 - (H) The location of the toilet facilities;
 - (I) The location of a break room and location of personal belonging lockers; and
 - (J) The location of all areas that may contain marijuana that shows walls, partitions, counters and all areas of ingress and egress. The blueprint shall also reflect all production, propagation, vegetation, flowering, harvesting, and manufacturing areas;
- (11) Proof acceptable to the commissioner that the applicant can establish and maintain an escrow account in a financial institution in Connecticut, a letter of credit drawn from a

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financial institution in Connecticut or a surety bond issued by a surety company licensed by the state of Connecticut Department of Insurance and of a capacity and rating acceptable to the commissioner;

(12) Documents related to any compassionate need program the producer intends to offer; and

(13) Such other documents and information reasonably required by the department to determine the applicant's suitability for licensing or to protect public health and safety.

(c) In the event any information contained in the producer license application or accompanying documents changes after being submitted to the department, the applicant shall notify the department in writing and provide corrected information in a timely manner so as not to disrupt the license selection process.

(d) The department may verify information contained in each application and accompanying documentation in order to assess the applicant's character and fitness to operate a production facility. The department may verify the information and assess the applicant's character and fitness by, among other things:

(1) Contacting the applicant by telephone, mail, electronic mail or such other means as are reasonable under the circumstances;

(2) Conducting an on-site visit of the proposed production facility location or other production facility locations associated with the applicant or the applicant's producer backers;

(3) Conducting background checks or contacting references of the applicant, the applicant's producer backers and the producer backers' members, shareholders or investors;

(4) Contacting state regulators in any other states where the applicant, the applicant's producer backers and the producer backers' members, shareholders or investors are engaged in, or have sought to be engaged in, any aspect of that state's medical marijuana program; and

(5) Requiring a personal meeting with the applicant and the submission of additional information or documents.

(Effective September 6, 2013)

Sec. 21a-408-22. Production facility employee registrations

(a) A production facility employee shall be at least 18 years of age and shall be registered by the department pursuant to section 21a-408-24 of the Regulations of Connecticut State Agencies before being employed by a producer.

(b) Any producer backer or other person who will exercise control over, or have management responsibility for, a production facility shall be registered with the department pursuant to section 21a-408-24 of the Regulations of Connecticut State Agencies.

(Effective September 6, 2013)

Sec. 21a-408-23. Notification of changes by producers

(a) Prior to adding any person as a producer backer or making any other change to the

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ownership of the production facility, the producer shall register such additional person, on forms prescribed by the commissioner, with the department pursuant to sections 21a-408-24 to 21a-408-25, inclusive, of the Regulations of Connecticut State Agencies, and pay the accompanying registration fee set forth for producer backers in section 21a-408-28 of the Regulations of Connecticut State Agencies. A producer shall not make such addition or change until approved by the commissioner.

(b) Prior to making any change to the producer name or production facility name, the producer shall submit an application, on a form prescribed by the commissioner, for such change to the department and pay the fee set forth in section 21a-408-28 of the Regulations of Connecticut State Agencies. A producer shall not make such change until approved by the commissioner.

(c) Prior to changing a production facility location, the producer shall submit an application, on a form prescribed by the commissioner, for such change to the department and pay the fee set forth in section 21a-408-28 of the Regulations of Connecticut State Agencies. A producer shall not make such change until approved by the commissioner.

(d) Prior to any modification, remodeling, expansion, reduction or other physical, non-cosmetic alteration of a production facility, the producer shall submit an application, on a form prescribed by the commissioner, for such change to the department and pay the fee set forth in section 21a-408-28 of the Regulations of Connecticut State Agencies. A producer shall not make such change until approved by the commissioner.

(e) The producer shall notify the department no later than ten business days after the date that a producer backer or production facility employee ceases to work for or be affiliated with the producer.

(f) The producer shall notify the department if the producer's production facility will be closing or if the producer does not intend to renew the producer's license immediately after such decision has been made. In no event shall such notification be given less than six months prior to the effective date of such closing.

(Effective September 6, 2013)

Sec. 21a-408-24. Licenses and registrations for dispensary facilities, dispensary facility employees, producers, producer backers and production facility employees

(a) Applicants for any of the licenses or registrations set forth in sections 21a-408-13 to 21a-408-24, inclusive, of the Regulations of Connecticut State Agencies, shall be required to supply information to the department sufficient for the department to conduct a background check and determine the character and fitness of the applicant for the license or registration, which information may include, but is not limited to:

- (1) Name;
- (2) Address;
- (3) Social security number or federal employee identification number;
- (4) Date of birth or formation;
- (5) Name and address of the producer, production facility or dispensary facility that the

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applicant seeks to work for, invest in or otherwise be associated with;

- (6) Past employment history;
- (7) Pharmacist or pharmacy technician license or registration number, if applicable;
- (8) Previous or current involvement in the medical marijuana industry;
- (9) Personal references;
- (10) Any criminal record;
- (11) Whether the person has ever applied for a license or registration related to medical marijuana in any state and, if so, the status of that application, license or registration;
- (12) Percent ownership or nature of the financial interest in the producer or dispensary facility, where applicable;
- (13) Detailed information regarding the applicant's financial position, indicating all assets, liabilities, income and net worth, to demonstrate the financial capacity of the applicant to build and operate a marijuana production facility or dispensary facility; and
- (14) Such other information as the department may reasonably require to determine the applicant's suitability for licensing or registration or to protect public health and safety.

(b) All licenses and registrations issued pursuant to sections 21a-408-13 to 21a-408-24 inclusive, of the Regulations of Connecticut State Agencies, shall expire one year after the date of issuance and annually thereafter if renewed.

(c) Any person who receives a license or registration pursuant to sections 21a-408-13 to 21a-408-24, inclusive, of the Regulations of Connecticut State Agencies, shall notify the department of any changes to the information supplied on the application for such license or registration no later than five business days after such change.

(Effective September 6, 2013)

Sec. 21a-408-25. Department issuance of identification cards; expiration

(a) The department shall issue each person licensed or registered pursuant to sections 21a-408-13 to 21a-408-24, inclusive, of the Regulations of Connecticut State Agencies an identification card that shall expire one year after the date of issuance.

(b) No person shall begin working at a dispensary facility or production facility prior to receiving their identification card.

(c) All licensees and registrants shall conspicuously display the identification cards issued by the department while on the premises of a dispensary facility or production facility.

(d) The dispensary facility manager or producer shall return to the department the identification card of any dispensary facility employee or production facility employee whose employment has been terminated no later than five business days after such termination.

(Effective September 6, 2013)

Sec. 21a-408-26. Non-transferability of licenses and registrations

No person issued a license or registration pursuant to 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies shall assign or transfer such license, or

registration without the commissioner's prior approval.

(Effective September 6, 2013)

Sec. 21a-408-27. Renewal applications

(a) Every person issued a license or registration pursuant to sections 21a-408-13 to 21a-408-24, inclusive, of the Regulations of Connecticut State Agencies shall file a renewal application and the proper fees as set forth in section 21a-408-28 of the Regulations of Connecticut State Agencies with the department at least 45 days prior to the date the existing license or registration expires.

(b) If a renewal application is not filed prior to the expiration date of the applicable license or registration, the license or registration shall expire and become void until the licensee or registrant files a renewal application and pays all applicable fees, and the renewal application is approved by the commissioner.

(c) If a renewal application and all applicable fees are submitted to the department more than thirty calendar days after the expiration of the license or registration, the commissioner shall not renew such license or registration and the applicant shall reapply for such license or registration.

(Effective September 6, 2013)

Sec. 21a-408-28. Fees

An applicant shall submit the following fees with each license and registration application submitted, in the form of a certified check or money order payable to the "Treasurer, State of Connecticut," or by such other means as approved by the commissioner:

(1) The non-refundable application fee and each renewal fee for each qualifying patient and for each primary caregiver application shall be twenty-five dollars. In addition, there shall be a non-refundable fee of seventy-five dollars for administrative costs for each qualifying patient application, for a total non-refundable fee of one hundred dollars per qualifying patient application and for each renewal.

(2) The non-refundable fee for a replacement registration certificate for a qualifying patient or primary caregiver whose information has changed or whose original registration certificate has been lost, stolen or destroyed shall be ten dollars;

(3) The non-refundable fee for a dispensary facility license application shall be one thousand dollars. In addition, upon approval of the applicant's dispensary facility license, the applicant shall pay an additional fee of five thousand dollars prior to receiving a license;

(4) The non-refundable fee for each renewal of a dispensary facility license shall be five thousand dollars;

(5) The non-refundable fee for a dispensary license and for each renewal shall be one hundred dollars;

(6) The non-refundable fee for a dispensary technician and dispensary employee registration and each renewal shall be fifty dollars;

(7) The non-refundable registration fee and each renewal fee for a dispensary facility

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backer shall be one hundred dollars;

(8) The non-refundable fee for an application to change a dispensary facility name shall be one hundred dollars;

(9) The non-refundable fee for a change of dispensary facility manager form shall be fifty dollars;

(10) The non-refundable fee for an application to expand or change the location of a dispensary facility shall be one thousand dollars. If the application is approved, the applicant shall pay an additional one thousand five hundred dollars upon such approval;

(11) The non-refundable fee for an application to make a physical, non-cosmetic alteration of a dispensary facility or a dispensary facility department, other than an expansion, shall be five hundred dollars;

(12) The non-refundable application fee for a producer license shall be twenty-five thousand dollars. In addition, if an application for a producer license is approved, the applicant shall pay a fee of seventy-five thousand dollars prior to receiving a license;

(13) The non-refundable fee for each renewal of a producer license shall be seventy-five thousand dollars per production facility location;

(14) The non-refundable application fee for a producer to open an additional production facility location shall be twenty-five thousand dollars. In addition, if an application for an additional location is approved, the applicant shall pay a fee of seventy-five thousand dollars prior to receiving permission to open an additional production facility.

(15) The non-refundable fee for a production facility employee registration and for each renewal shall be one hundred dollars;

(16) The non-refundable fee for a producer backer registration and for each renewal shall be one hundred dollars;

(17) The non-refundable fee for an application to change a producer name or production facility name shall be one hundred dollars;

(18) The non-refundable fee for an application to expand or change the location of a production facility shall be three thousand five hundred dollars. In addition, upon approval of the application, the applicant shall pay an additional fee of one thousand five hundred dollars;

(19) The non-refundable fee for an application to make a physical, non-cosmetic alteration of a production facility, other than an expansion, shall be five hundred dollars; and

(20) The non-refundable fee for a producer to register a marijuana brand name with the department shall be twenty five dollars per brand name.

(Effective September 6, 2013)

Sec. 21a-408-29. Escrow Account Terms

(a) The producer's two million dollar escrow account, letter of credit or surety bond shall be payable to the state of Connecticut in the event the commissioner determines, after a hearing pursuant to the Uniform Administrative Procedure Act, sections 4-166 to 4-189,

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inclusive, of the Connecticut General Statutes, that the producer has failed to timely and successfully complete the construction of a production facility or to continue to operate such facility in a manner that provides a substantially uninterrupted supply to its usual dispensary facility customers during the term of the license.

(b) In addition to the other terms and conditions permitted by the Act and sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies, the commissioner shall permit the producer's two million dollar escrow account, letter of credit or surety bond to be reduced by five-hundred thousand dollars upon the successful achievement of each of the following milestones, resulting in a potential elimination in the escrow account, letter of credit or surety bond:

(1) A determination by the commissioner that the production facility is fully operational and able to commence production of marijuana as provided for in the license application of the producer;

(2) A determination by the commissioner that the production facility remained operational without substantial interruption and without any violation of the Act or sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies for a one year period;

(3) A determination by the commissioner that the production facility remained operational without substantial interruption and without any violation of the Act or sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies for an additional two consecutive years; and

(4) A determination by the commissioner that the production facility remained operational without substantial interruption and without any violation of the Act or sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies for a second period of two consecutive years.

(c) If a producer voluntarily chooses not to renew the producer license and provides notice of this decision in accordance with section 21a-408-23(f) of the Regulations of Connecticut State Agencies, the commissioner shall extinguish the obligations under the escrow account, letter of credit or surety bond at the end of the license term.

(Effective September 6, 2013)

Sec. 21a-408-30. Refusal to renew or issue a license or registration of a dispensary facility, dispensary facility employee, producer or production facility employee

(a) If the commissioner refuses to renew a dispensary facility license or producer license, the department shall, in accordance with the Uniform Administrative Procedure Act , sections 4-166 to 4-189, inclusive, of the Connecticut General Statutes, notify the licensee of its refusal and set a day and place of a hearing thereon giving the licensee reasonable notice in advance thereof. If, at or after such hearing, the commissioner refuses to renew the license, the department shall promptly provide notice of such decision to such licensee.

(b) Upon refusal to issue or renew a license or registration required under sections 21a-408-13 to 21a-408-24, inclusive, of the Regulations of Connecticut State Agencies, other

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than dispensary facility licenses and producer licenses, the department shall provide the applicant, licensee or registrant with notice of the grounds for the refusal to issue or renew such person's license or registration and shall inform the person of the right to request a hearing.

(1) Upon receipt of such notice, the applicant, licensee or registrant may request a hearing, which request shall be submitted to the department in writing not more than ten calendar days after the date of the notice.

(2) If a request for a hearing is made within the ten-day period, the department shall conduct a hearing in accordance with the Uniform Administrative Procedure Act, sections 4-166 to 4-189, inclusive, of the Connecticut General Statutes.

(3) If the applicant, licensee or registrant does not request a hearing in writing within the ten-day period, the applicant shall be deemed to have waived the right to a hearing.

(Effective September 6, 2013)

Sec. 21a-408-31. Disciplinary action against dispensary facility, dispensary facility employee, producer or production facility employee

(a) For sufficient cause found in accordance with subsection (b) of this section, the commissioner may, in the commissioner's discretion, suspend, revoke or refuse to grant or renew a license or registration issued pursuant to sections 21a-408-13 to 21a-408-24, inclusive, of the Regulations of Connecticut State Agencies, or place such license or registration on probation, place conditions on such license or registration, or take other actions permitted by statute or regulation. For purposes of this section, each instance of qualifying patient or primary caregiver contact or consultation that is in violation of any provision of sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies, shall be deemed a separate offense. Failure to renew any license or registration in a timely manner is not a violation for purposes of this section.

(b) Any of the following shall be sufficient cause for such action by the commissioner:

(1) Furnishing of false or fraudulent information in any application;

(2) Any criminal conviction under federal or state statutes, or regulations or local ordinances, unless the act subject to the conviction occurred when the person held a valid license or registration certificate issued pursuant to the Act and sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies and the conviction was based on a federal statute or regulation related to the possession, purchase or sale of marijuana that is authorized under the Act and sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies;

(3) Any civil action under any federal or state statute, or regulation or local ordinance relating to the applicant's, licensee's or registrant's profession, or involving drugs, medical devices or fraudulent practices, including, but not limited to, fraudulent billing practices;

(4) Failure to maintain effective controls against diversion, theft or loss of marijuana or other controlled substances;

(5) Discipline by, or a pending disciplinary action or unresolved complaint, with regard

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to any professional license or registration of any federal, state or local government;

- (6) Abuse or excessive use of drugs or alcohol;
- (7) Possession, use, prescription for use or distribution of controlled substances or legend drugs, except for therapeutic or other proper medical or scientific purpose;
- (8) Failure to account for the disposition of marijuana;
- (9) Failure to keep accurate records of all marijuana dispensed, administered or sold to qualifying patients or primary caregivers;
- (10) Failure to keep accurate records of all marijuana produced, manufactured, packaged or sold to a dispensary or dispensary facility;
- (11) Denial, suspension or revocation of a license or registration, or the denial of a renewal of a license or registration, by any federal, state or local government or a foreign jurisdiction;
- (12) False, misleading or deceptive representations to the public or the commissioner or the commissioner's authorized representative;
- (13) Return to regular stock of any marijuana where:
 - (A) The package or container containing the marijuana has been opened, breached or tampered with; or
 - (B) The marijuana has been sold to a patient or caregiver;
- (14) Involvement in a fraudulent or deceitful practice or transaction;
- (15) Performance of incompetent or negligent work;
- (16) Failure to maintain the entire dispensary facility or production facility and contents in a clean, orderly and sanitary condition;
- (17) Intentionally, or through negligence, obscuring, damaging, or defacing a license or registration card;
- (18) A determination by the commissioner that the applicant or holder of the license or registration has a condition, including, but not limited to, physical illness or loss of skill or deterioration due to the aging process, emotional disorder or mental illness, abuse or excessive use of drugs or alcohol that would interfere with the practice of dispensing, operation of a dispensary facility or activities as a dispensary, dispensary technician, dispensary facility employee, producer or production facility employee, provided the department shall not, in taking action against a license or registration holder on the basis of such a condition, violate the provisions of section 46a-73 of the Connecticut General Statutes, or 42 USC 12132 of the federal Americans with Disabilities Act;
- (19) Permitting another person to use the licensee's or registrant's license or registration;
- (20) Failure to cooperate or give information to the department, local law enforcement authorities or any other enforcement agency upon any matter arising out of conduct at a dispensary facility or production facility;
- (21) Discontinuance of business for more than sixty days, unless the commissioner approves an extension of such period for good cause shown, upon a written request from a dispensary facility or producer. Good cause includes exigent circumstances that necessitate the closing of the facility. Good cause shall not include a voluntary closing of the dispensary

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facility or production facility;

(22) A violation of any provision of the Connecticut General Statutes, or any regulation established thereunder, related to the person's profession or occupation; or

(23) Failure to comply with any provision of sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies.

(c) No person whose application for a license or registration has been denied due to the applicant's character and fitness may make another application for a license or registration under sections 21a-408-13 to 21a-408-24, inclusive, of the Regulations of Connecticut State Agencies for at least one year from the date of denial.

(d) No person whose license or registration has been revoked may make an application for a license or registration under sections 21a-408-13 to 21a-408-24, inclusive, of the Regulations of Connecticut State Agencies for at least one year from the date of such revocation.

(e) If a license or registration is voluntarily surrendered or is not renewed, the commissioner shall not be prohibited from suspending, revoking or imposing other penalties permitted by the Act and sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies, on any such license or registration.

(Effective September 6, 2013)

Sec. 21a-408-32. Suspension of dispensary facility license or producer license

During the period of any suspension of a dispensary facility license or producer license as a result of disciplinary action by the department:

(1) No person issued a dispensary facility license shall alter the dispensary facility, unless the alterations have been expressly approved in writing by the commissioner, or attach to the exterior or any other part of the facility any sign indicating that the premises are "closed for repairs," "closed for alterations" or any like signs.

(2) The dispensary facility manager shall place on the dispensary facility in the front window, or on the front door facing the street, a notice indicating the length of the suspension and the reasons therefor. The sign shall measure a minimum of eight inches in height by ten inches in width and the lettering shall be in a size and style that allows such sign to be read without difficulty by persons standing outside the dispensary facility. The dispensary facility manager shall maintain the sign in place until the period of suspension has terminated.

(3) A dispensary facility shall not offer, sell, order or receive marijuana products unless expressly approved by the commissioner.

(4) The dispensary facility manager shall close the entire dispensary facility for business and shall securely lock all marijuana products. Dispensary facility employees may visit the facility only for the necessary care and maintenance of the premises.

(5) A producer whose license has been suspended shall not sell, offer for sale, or deliver marijuana to any dispensary facility. Production facility employees may enter the premises of the production facility for the necessary care and maintenance of the premises and of

any marijuana and marijuana products.

(6) The commissioner may, in the commissioner's discretion, accept a monetary payment as an offer in compromise in lieu of, or so as to reduce a suspension, from a licensee or registrant whose license or registration is subject to a hearing that may result in a suspension or whose license or registration has been suspended after due hearing. Such offer shall include a waiver of appeal and judicial review and a certified check in the amount designated by the commissioner.

(Effective September 6, 2013)

Sec. 21a-408-33. Confidentiality of information

(a) Except as provided by section 21a-408-50 of the Regulations of Connecticut State Agencies, a dispensary facility employee, producer, production facility employee, or any other person associated with a dispensary facility or producer, shall not disclose patient-specific information received and records kept pursuant to sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies, except that such person shall disclose patient treatment or dispensing information to:

(1) The department or state and local law enforcement for purposes of investigating and enforcing the Act or sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies;

(2) Physicians, pharmacists or other dispensaries for the purpose of providing patient care and drug therapy management and monitoring controlled substances obtained by the qualifying patient;

(3) A qualifying patient but only with respect to information related to such patient;

(4) A primary caregiver, but only with respect to the qualifying patient of such primary caregiver;

(5) Third party payors who pay claims for dispensary services rendered to a qualifying patient or who have a formal agreement or contract to audit any records or information in connection with such claims;

(6) Any person, the state or federal government or any agency thereof pursuant to an order of a court of competent jurisdiction or pursuant to a search warrant; and

(7) Any person upon the express written consent of the patient and only with respect to information related to such patient. Such written consent shall clearly identify the specific person and purpose for which consent is being granted, but in no event shall such information be disclosed to an electronic data intermediary.

(b) An electronic data intermediary shall not have access to any data involving marijuana, qualifying patients, primary caregivers or other data from a dispensary facility or an agent of the dispensary facility.

(c) No electronic equipment utilized by a dispensary department shall collect patient-specific data for use outside the dispensary department, except that such data shall be disclosed to the commissioner or the commissioner's authorized representative for purposes

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of an inspection or investigation.

(Effective September 6, 2013)

Sec. 21a-408-34. Operation of dispensary facility

(a) No person may operate a dispensary facility without a dispensary facility license issued by the department.

(b) A dispensary facility shall not dispense marijuana from, obtain marijuana from, or transfer marijuana to, a location outside of the state of Connecticut.

(c) A dispensary facility shall not obtain, cultivate, deliver, transfer, transport, sell or dispense marijuana except:

(1) It may acquire marijuana from a producer; and

(2) It may dispense and sell marijuana to a qualifying patient or primary caregiver who is registered with the department pursuant to the Act and section 21a-408-6 of the Regulations of Connecticut State Agencies.

(d) No person at a dispensary facility shall provide marijuana samples or engage in marijuana compounding.

(e) A dispensary facility shall sell marijuana products only in the original sealed containers or packaging as delivered by the producer, except that a dispensary may remove the marijuana product from the producer's child-resistant container or package and place the marijuana product in a non-child-resistant, secure and light-resistant container upon a written request from the qualifying patient or primary caregiver so long as all original labeling is maintained with the product.

(f) Only a dispensary may dispense marijuana, and only a dispensary or dispensary technician may sell marijuana, to qualifying patients and primary caregivers who are registered with the department pursuant to the Act and section 21a-408-6 of the Regulations of Connecticut State Agencies. A dispensary technician may assist, under the direct supervision of a dispensary, in the dispensing of marijuana.

(g) A dispensary facility shall place all products sold to the qualifying patient or primary caregiver in an opaque package that shall not indicate the contents of the package, the originating facility or in any other way cause another person to believe that the package may contain marijuana.

(h) A dispensary facility shall not permit any person to enter the dispensary department unless:

(1) Such person is licensed or registered by the department pursuant to 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies;

(2) Such person's responsibilities necessitate access to the dispensary department and then for only as long as necessary to perform the person's job duties; or

(3) Such person has a patient or caregiver registration certificate, in which case such person shall not be permitted behind the service counter or in other areas where marijuana is stored.

(i) All dispensary facility employees shall, at all times while at the dispensary facility,

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have their current dispensary license, dispensary technician registration or dispensary facility employee registration available for inspection by the commissioner or the commissioner's authorized representative.

(j) While inside the dispensary facility, all dispensary facility employees shall wear name tags or similar forms of identification that clearly identify them to the public, including their position at the dispensary facility.

(k) A dispensary department shall be open for qualifying patients and primary caregivers to purchase marijuana products for a minimum of thirty-five hours a week, except as otherwise authorized by the commissioner.

(l) A dispensary department that closes during its normal hours of operation shall implement procedures to notify qualifying patients and primary caregivers of when the dispensary department will resume normal hours of operation. Such procedures may include, but are not limited to, telephone system messages and conspicuously posted signs. If the dispensary department is, or will be, closed during its normal hours of operation for longer than two business days, the dispensary facility shall immediately notify the department.

(m) A dispensary facility that operates at times when the dispensary department is closed shall:

(1) Conspicuously post the hours of operation of the dispensary department at all entrances to the dispensary facility in block letters at least one-half inch in height; and

(2) Clearly state the hours of operation of the dispensary department in all advertising for the specific dispensary department or dispensary facility.

(n) A dispensary facility shall make publicly available the price of all marijuana products offered by the dispensary facility to prospective qualifying patients and primary caregivers. Such disclosure may include posting the information on the dispensary facility Internet web site.

(o) A dispensary facility shall provide information to qualifying patients and primary caregivers regarding the possession and use of marijuana. The dispensary facility manager shall submit all informational material to the commissioner for approval prior to being provided to qualifying patients and primary caregivers. Such informational material shall include information related to:

(1) Limitations on the right to possess and use marijuana pursuant to the Act and sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies;

(2) Safe techniques for proper use of marijuana and paraphernalia;

(3) Alternative methods and forms of consumption or inhalation by which one can use marijuana;

(4) Signs and symptoms of substance abuse; and

(5) Opportunities to participate in substance abuse programs.

(p) The dispensary facility shall establish, implement and adhere to a written alcohol-free, drug-free and smoke-free work place policy, which shall be available to the commissioner or the commissioner's authorized representative upon request.

(q) All deliveries from producers shall be carried out under the direct supervision of a

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dispensary who shall be present to accept the delivery. Upon delivery, the marijuana shall immediately be placed in an approved safe or approved vault within the dispensary department where marijuana is stored.

(Effective September 6, 2013)

Sec. 21a-408-35. Dispensary facility prohibitions

(a) No dispensary department shall be open or in operation, and no person shall be in the dispensary department, unless a dispensary is on the premises and directly supervising the activity within the dispensary department. At all other times, the dispensary department shall be closed and properly secured, in accordance with sections 21a-408-51 and 21a-408-62 of the Regulations of Connecticut State Agencies.

(b) No dispensary facility shall sell anything other than marijuana products and paraphernalia from the dispensary department.

(c) No marijuana shall be consumed on the premises of a dispensary facility.

(d) No food or beverages shall be consumed by qualifying patients or primary caregivers on the premises of a dispensary facility, except that complimentary food and non-alcoholic beverages may be available for qualifying patients and primary caregivers who are at the dispensary facility for a pre-scheduled education, counseling or therapy program.

(e) No person, except for a qualifying patient or primary caregiver, shall open or break the seal placed on a marijuana product packaged by a producer except that a dispensary may remove marijuana from a child-resistant container or package under the conditions set forth in sections 21a-408-34(e) of the Regulations of Connecticut State Agencies.

(f) Except as provided in subsection (g) of this section, no person, except a dispensary facility employee, or a production facility employee who is delivering marijuana products, shall be allowed on the premises of a dispensary facility without a qualifying patient or primary caregiver registration certificate issued by the department.

(g) (1) Upon prior written request, the commissioner or the commissioner's authorized representative may waive the provisions of subsection (f) of this section.

(2) All persons not permitted on the premises of a dispensary facility pursuant to subsection (f) of this section, but who have been authorized, in writing, to enter the facility by the commissioner or the commissioner's authorized representative shall obtain a visitor identification badge from a dispensary facility employee, prior to entering the dispensary facility. A dispensary or dispensary technician shall escort and monitor such a visitor at all times the visitor is in the dispensary department. A visitor shall visibly display the visitor identification badge at all times the visitor is in the dispensary facility and shall return the visitor identification badge to a dispensary facility employee upon exiting the dispensary facility.

(3) All visitors shall log in and out. The dispensary facility shall maintain the visitor log, which shall include the date, time and purpose of the visit and which shall be available to the commissioner in accordance with section 21a-408-70 of the Regulations of Connecticut State Agencies.

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(4) If an emergency requires the presence of a visitor and makes it impractical for the dispensary facility to obtain a waiver pursuant to subsection (g)(1) of this section, the dispensary facility shall provide written notice to the commissioner as soon as practicable after the onset of the emergency. Such notice shall include the name and company affiliation of the visitor, the purpose of the visit, and the date and time of the visit. A dispensary facility shall monitor the visitor and maintain a log of such visit as required by this subsection.

(h) No person associated with a dispensary facility shall enter into any agreement with a certifying physician or health care facility concerning the provision of services or equipment that may adversely affect any person's freedom to choose the dispensary facility at which the qualifying patient or primary caregiver will purchase marijuana.

(i) No marijuana shall be sold, dispensed or distributed via a delivery service or any other manner outside of a dispensary facility, except that a primary caregiver may deliver marijuana to the caregiver's qualified patient.

(j) Notwithstanding the requirements of sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies, members of the department, local law enforcement or other federal, state of Connecticut or local government officials may enter any area of a dispensary facility if necessary to perform their governmental duties.

(Effective September 6, 2013)

Sec. 21a-408-36. Procedures when dispensary department is closed

(a) During times that the dispensary department is closed, it shall be securely locked and equipped with an alarm system. Such alarm shall be activated and operated separately from any other alarm system at the dispensary facility and shall be able to immediately detect entrance to the dispensary department at times when it is closed. Keys and access codes to the alarm system shall be controlled in such a manner so as to prevent access to the dispensary department by other than authorized dispensary facility employees. Only a dispensary shall have the authority to deactivate the alarm system.

(b) A dispensary facility shall store marijuana in an approved safe or approved vault within the dispensary department and shall not sell marijuana products when the dispensary department is closed.

(Effective September 6, 2013)

Sec. 21a-408-37. Security of the dispensary department during momentary absences of a dispensary

During times when the dispensary leaves the dispensary department for a few moments, the dispensary shall take measures to ensure that adequate security of the dispensary department is provided and that entry by unauthorized persons is prevented or immediately detected. The presence of a dispensary technician in the dispensary department during these times shall be considered adequate security. If no such dispensary technician is available for this purpose, and the dispensary department is not within the view of the dispensary, the dispensary shall physically or electronically secure the dispensary department through

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the use of mechanisms such as a locked barrier or an alarm system that will prevent or immediately detect access to such department.

(Effective September 6, 2013)

Sec. 21a-408-38. Rights and responsibilities of dispensaries

(a) A dispensary, in good faith, may sell and dispense marijuana to any qualifying patient or primary caregiver that is registered with the department. Except as otherwise provided by sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies, the dispensary dispensing the marijuana shall include the date of dispensing and the dispensary's signature or initials on the dispensary facility's dispensing record log.

(b) All dispensaries shall register with the department to access the prescription monitoring program.

(c) A dispensary shall review a qualifying patient's controlled substance history report within the prescription monitoring program before dispensing any marijuana to the qualifying patient or the qualifying patient's primary caregiver.

(d) A dispensary shall exercise professional judgment to determine whether to dispense marijuana to a qualifying patient or primary caregiver if the dispensary suspects that dispensing marijuana to the qualifying patient or primary caregiver may have negative health or safety consequences for the qualifying patient or the public.

(e) A dispensary may dispense a portion of a qualifying patient's one-month supply of marijuana. The dispensary may dispense the remaining portion of the one-month supply of marijuana at any time except that no qualifying patient or primary caregiver shall receive more than a one-month supply of marijuana in a one-month period.

(f) A dispensary, or dispensary technician, shall require the presentation of a registration certificate together with another valid photographic identification issued to a qualifying patient or primary caregiver, prior to selling marijuana to such qualifying patient or primary caregiver.

(g) A dispensary shall document a qualifying patient's self-assessment of the effects of marijuana in treating the qualifying patient's debilitating medical condition or the symptoms thereof. A dispensary facility shall maintain such documentation electronically for at least three years following the date the patient ceases to designate the dispensary facility and such documentation shall be made available in accordance with section 21a-408-70 of the Regulations of Connecticut State Agencies.

(Effective September 6, 2013)

Sec. 21a-408-39. Dispensaries to assign serial number and maintain records.

Transfer of records to another dispensary facility

(a) A dispensary shall assign and record a sequential serial number to each marijuana product dispensed to a patient and shall keep all dispensing records in numerical order in a suitable file, electronic file or ledger. The records shall indicate:

- (1) The date of dispensing;

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- (2) The name and address of the certifying physician;
- (3) The name and address of the qualifying patient, or primary caregiver if applicable;
- (4) The initials of the dispensary who dispensed the marijuana; and
- (5) Whether a full or partial one-month supply of marijuana was dispensed.

(b) A dispensary facility shall maintain records created under this section and shall make such records available in accordance with section 21a-408-70 of the Regulations of Connecticut State Agencies.

(c) When a dispensary department closes temporarily or permanently, the dispensary facility shall, in the interest of public health, safety and convenience, make its complete dispensing records immediately available to a nearby dispensary facility and post a notice of this availability on the window or door of the closed dispensary facility. The dispensary facility shall simultaneously provide such notice to the commissioner.

(Effective September 6, 2013)

Sec. 21a-408-40. Labeling of marijuana products by dispensary

(a) A dispensary shall not dispense marijuana that does not bear the producer label required pursuant to section 21a-408-56 of the Regulations of Connecticut State Agencies.

(b) A dispensary, or a dispensary technician under the direct supervision of the dispensary, shall completely and properly label all marijuana products dispensed with all required information as follows:

- (1) The serial number, as assigned by the dispensary facility;
- (2) The date of dispensing the marijuana;
- (3) The quantity of marijuana dispensed;
- (4) The name and registration certificate number of the qualifying patient and, where applicable, the primary caregiver;
- (5) The name of the certifying physician;
- (6) Such directions for use as may be included in the physician's written certification or otherwise provided by the physician;
- (7) Name of the dispensary;
- (8) Name and address of the dispensary facility;
- (9) Any cautionary statement as may be required by Connecticut state statute or regulation; and
- (10) A prominently printed expiration date based on the producer's recommended conditions of use and storage that can be read and understood by the ordinary individual.

(c) The expiration date required by this section shall be no later than the expiration date determined by the producer.

(d) No person except a dispensary, or a dispensary technician operating under the direct supervision of a dispensary, shall alter, deface or remove any label so affixed.

(Effective September 6, 2013)

Sec. 21a-408-41. Responsibilities of dispensary facility manager

(a) A dispensary facility shall employ the dispensary facility manager at the dispensary facility for at least thirty-five hours per week, except as otherwise authorized by the commissioner.

(b) No person shall be a dispensary facility manager for more than one dispensary facility at a time.

(c) The dispensary facility manager shall be responsible for ensuring that:

(1) Dispensary technicians are registered and properly trained;

(2) All record-retention requirements are met;

(3) All requirements for the physical security of marijuana are met;

(4) The dispensary facility has appropriate pharmaceutical reference materials to ensure that marijuana can be properly dispensed;

(5) The following items are conspicuously posted in the dispensary department in a location and in a manner so as to be clearly and readily identifiable to qualifying patients and primary caregivers:

(A) Dispensary facility license;

(B) The name of the dispensary facility manager; and

(C) The price of all marijuana products offered by the dispensary facility as identified by their registered brand name as set forth in section 21a-408-59 of the Regulations of Connecticut State Agencies; and

(6) Any other filings or notifications required to be made on behalf of the dispensary facility as set forth in sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies, are completed.

(Effective September 6, 2013)

Sec. 21a-408-42. Dispensary technicians. Ratio. Supervision and responsibility

(a) The ratio of dispensary technicians to dispensaries on duty in a dispensary department shall not exceed three dispensary technicians to one dispensary.

(b) A dispensary whose license is under suspension or revocation shall not act as a dispensary technician.

(c) The dispensary providing direct supervision of dispensary technicians shall be responsible for the dispensary technicians' actions. Any violations relating to the dispensing of marijuana resulting from the actions of a dispensary technician, or the use of dispensary technicians in the performance of tasks in a manner not in conformance with sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies, shall constitute cause for action against the license of the dispensary. As used in this subsection, "direct supervision" means a supervising dispensary who:

(1) Is physically present in the area or location where the dispensary technician is performing routine marijuana dispensing functions; and

(2) Conducts in-process and final checks on the dispensary technician's performance.

(Effective September 6, 2013)

Sec. 21a-408-43. Dispensary technician limitations

(a) Dispensary technicians shall not:

(1) Consult with a qualifying patient or the patient's primary caregiver regarding marijuana or other drugs, either before or after marijuana has been dispensed, or regarding any medical information contained in a patient medication record;

(2) Consult with the physician who certified the qualifying patient, or the physician's agent, regarding a patient or any medical information pertaining to the patient's marijuana or any other drug the patient may be taking;

(3) Interpret the patient's clinical data or provide medical advice;

(4) Perform professional consultation with physicians, nurses or other health care professionals or their authorized agents; or

(5) Determine whether a different brand or formulation of marijuana should be substituted for the marijuana product or formulation recommended by the physician or requested by the qualifying patient or primary caregiver.

(b) Notwithstanding subsection (a) of this section, a dispensary technician may communicate with a physician who certified a qualifying patient, or the physician's agent, to obtain a clarification on a qualifying patient's written certification or instructions provided the supervising dispensary is aware that such clarification is being requested.

(Effective September 6, 2013)

Sec. 21a-408-44. Dispensary technician training

(a) Dispensary technicians shall complete initial training as determined by the dispensary facility manager of each dispensary facility. Such training shall include, but not be limited to:

(1) On-the-job and other related education, which shall be commensurate with the tasks dispensary technicians are to perform and which shall be completed prior to the regular performance of such tasks;

(2) Professional conduct, ethics, and state and federal statutes and regulations regarding patient confidentiality; and

(3) Developments in the field of the medical use of marijuana.

(b) The dispensary technician shall be registered as a dispensary technician with the department prior to the start of such training.

(c) The dispensary facility manager shall assure the continued competency of dispensary technicians through continuing in-service training designed to supplement initial training, which shall include any guidance specified by the department.

(d) The dispensary facility manager shall be responsible for maintaining a written record documenting the initial and continuing training of dispensary technicians, which shall contain:

(1) The name of the person receiving the training;

(2) The dates of the training;

(3) A general description of the topics covered;

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(4) The name of the person supervising the training; and
(5) The signatures of the person receiving the training and the dispensary facility manager.

(e) When a change of dispensary facility manager occurs, the new manager shall review the training record and sign it, indicating that the new manager understands its contents.

(f) A dispensary facility shall maintain the record documenting the dispensary technician training and make it available in accordance with section 21a-408-70 of the Regulations of Connecticut State Agencies.

(Effective September 6, 2013)

Sec. 21a-408-45. Dispensary facility employee training. Employee records

(a) A dispensary facility shall provide to each dispensary facility employee, prior to the employee commencing work at the dispensary facility, at a minimum, training in the following:

(1) The proper use of security measures and controls that have been adopted for the prevention of diversion, theft or loss of marijuana;

(2) Procedures and instructions for responding to an emergency; and

(3) State and federal statutes and regulations regarding patient confidentiality.

(b) Each dispensary facility shall maintain and make available in accordance with section 21a-408-70 of the Regulations of Connecticut State Agencies, a training record for each dispensary facility employee. Such record shall include, at a minimum, documentation of all required training, including:

(1) The name of the person receiving the training;

(2) The dates of the training;

(3) A general description of the topics covered;

(4) The name of the person supervising the training; and

(5) The signatures of the person receiving the training and the dispensary facility manager.

(Effective September 6, 2013)

Sec. 21a-408-46. Dispensary facility manager notifications

(a) A dispensary facility shall immediately notify the department whenever the dispensary facility manager ceases such management and shall immediately designate with the department the name, address and license number of the dispensary who assumes management of the dispensary facility. A dispensary facility shall file the notice of change in management of a dispensary on a form prescribed by the commissioner and shall pay the filing fee required in section 21a-408-28 of the Regulations of Connecticut State Agencies. The dispensary who ceases management of the dispensary facility shall also immediately notify the department of that fact.

(b) If a dispensary facility manager is absent from the dispensary facility for any reason for more than sixteen consecutive days, the dispensary facility shall immediately report

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such absence to the department. The dispensary facility shall provide the department with the name of the dispensary designated to be the acting dispensary facility manager no later than five days after the sixteenth consecutive day of the original dispensary facility manager's absence.

(c) If the absence of the dispensary facility manager exceeds forty-two consecutive days, such person shall be deemed to have ceased to be the dispensary facility manager for the dispensary facility. In such case, the dispensary facility shall, in accordance with this section, immediately notify the department of the name, address and license number of the dispensary who is assuming management of the dispensary facility. A dispensary facility shall file the notice of change of dispensary facility manager on a form prescribed by the commissioner and shall pay the filing fee required by section 21a-408-28 of the Regulations of Connecticut State Agencies. The dispensary who ceases management of the dispensary facility shall also immediately notify the department of that fact.

(Effective September 6, 2013)

Sec. 21a-408-47. Dispensing error reporting. Quality assurance program

(a) A dispensary facility shall display a sign concerning the reporting of dispensing errors in a conspicuous location visible to qualifying patients and primary caregivers. The sign shall measure a minimum of eight inches in height and ten inches in width and the lettering shall be in a size and style that allows such sign to be read without difficulty by consumers standing at the dispensary department. The sign shall bear the following statement: "If you have a concern that an error may have occurred in the dispensing of your marijuana, you may contact the Department of Consumer Protection, Drug Control Division, by calling (Department of Consumer Protection telephone number authorized pursuant to section 21a-2 of the Connecticut General Statutes)."

(b) A dispensary facility shall include the following printed statement on the receipt or in the bag or other similar packaging in which marijuana is contained: "If you have a concern that an error may have occurred in the dispensing of your marijuana, you may contact the Department of Consumer Protection, Drug Control Division, by calling (Department of Consumer Protection telephone number authorized pursuant to section 21a-2 of the Connecticut General Statutes)." The dispensary facility shall print such statement in a size and style that allows it to be read without difficulty by patients.

(c) A dispensary facility shall implement and comply with a quality assurance program that describes, in writing, policies and procedures to detect, identify and prevent dispensing errors. A dispensary facility shall provide to the commissioner a written copy of such quality assurance program, shall distribute it to all dispensary facility employees, and shall make it readily available on the premises of the dispensary facility. Such policies and procedures shall include:

(1) Directions for communicating the details of a dispensing error to the physician who certified a qualifying patient and to the qualifying patient, the patient's primary caregiver or appropriate family member if the patient is deceased or is unable to fully comprehend

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the communication. Such communication shall describe methods of correcting the dispensing error or reducing the negative impact of the error on the qualifying patient; and

(2) A process to document and assess dispensing errors to determine the cause of the error and an appropriate response.

(d) A dispensary facility shall use the findings of its quality assurance program to develop dispensary systems and workflow processes designed to prevent dispensing errors.

(e) A dispensary facility manager shall inform dispensary facility employees of changes to dispensary facility policy, procedure, systems, or processes made as a result of recommendations generated by the quality assurance program.

(Effective September 6, 2013)

Sec. 21a-408-48. Review of dispensing errors

(a) A dispensary facility manager shall notify all dispensary employees that the discovery or reporting of a dispensing error shall be relayed immediately to a dispensary on duty.

(b) A dispensary facility manager shall ensure that a dispensary performs a quality assurance review for each dispensing error. A dispensary shall commence such review as soon as is reasonably possible, but no later than two business days from the date the dispensing error is discovered.

(c) A dispensary facility manager shall create a record of every quality assurance review. This record shall contain at least the following:

(1) The date or dates of the quality assurance review and the names and titles of the persons performing the review;

(2) The pertinent data and other information relating to the dispensing error reviewed;

(3) Documentation of contact with the qualifying patient, primary caregiver where applicable, and the physician who certified the patient as required by the quality assurance program implemented pursuant to section 21a-408-47 of the Regulations of Connecticut State Agencies;

(4) The findings and determinations generated by the quality assurance review; and

(5) Recommended changes to dispensary facility policy, procedure, systems, or processes, if any.

(d) A dispensary facility shall maintain quality assurance review records in an orderly manner and filed by date.

(e) A dispensary facility shall maintain a copy of the dispensary facility's quality assurance program and records of all reported dispensing errors and quality assurance reviews and make such documents available in accordance with section 21a-408-70 of the Regulations of Connecticut State Agencies.

(Effective September 6, 2013)

Sec. 21a-408-49. Electronic system record-keeping safeguards

(a) If a dispensary facility uses an electronic system for the storage and retrieval of patient information or other marijuana records, the dispensary facility shall use a system that:

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- (1) Guarantees the confidentiality of the information contained therein;
- (2) Is capable of providing safeguards against erasures and unauthorized changes in data after the information has been entered and verified by the dispensary; and
- (3) Is capable of being reconstructed in the event of a computer malfunction or accident resulting in the destruction of the data bank.

(Effective September 6, 2013)

Sec. 21a-408-50. Dispensary reporting into the prescription monitoring program

(a) At least once per day, a dispensary shall transmit electronically to the Drug Control Division of the department the information set forth in the most recent edition of the Standard for Prescription Monitoring Programs established by the American Society for Automation in Pharmacy, a copy of which may be purchased from the American Society for Automation in Pharmacy on their Internet web site: www.asapnet.org.

(b) A dispensary shall transmit to the department, in a format approved by the department, the fields listed in this subsection, including, but not limited to, the following:

- (1) Drug Enforcement Administration Pharmacy number, which shall be populated by a number provided by the department;
- (2) Birth date;
- (3) Sex code;
- (4) Date order filled, which shall be the date marijuana is dispensed;
- (5) Order number, which shall be the serial number assigned to each marijuana product dispensed to a patient;
- (6) New-refill code;
- (7) Quantity;
- (8) Days supply;
- (9) National Drug Code number, which shall be provided by the department;
- (10) Drug Enforcement Administration Prescriber identification number;
- (11) Date order written, which shall be the date the written certification was issued;
- (12) Number of refills authorized;
- (13) Order origin code, which shall be provided by the department;
- (14) Patient last name;
- (15) Patient first name;
- (16) Patient street address;
- (17) State;
- (18) Payment code for either cash or third-party provider; and
- (19) Drug name, which shall be the brand name of the marijuana product.

(c) A dispensary shall transmit the information required pursuant to this section in such a manner as to insure the confidentiality of the information in compliance with all federal and Connecticut state statutes and regulations, including the federal Health Insurance Portability and Accountability Act of 1996, Public Law 104-191.

(Effective September 6, 2013)

Sec. 21a-408-51. Security requirements for dispensary facilities

(a) A dispensary facility shall:

(1) Not maintain marijuana in excess of the quantity required for normal, efficient operation;

(2) Store all marijuana in an approved safe or approved vault and in such a manner as to prevent diversion, theft or loss;

(3) Maintain all marijuana in a secure area or location accessible only to specifically authorized employees, which shall include only the minimum number of employees essential for efficient operation;

(4) Keep all approved safes and approved vaults securely locked and protected from entry, except for the actual time required to remove or replace marijuana;

(5) Keep all locks and security equipment in good working order;

(6) Not allow keys to be left in the locks and not store or place keys in a location accessible to persons other than specifically authorized employees;

(7) Not allow other security measures, such as combination numbers, passwords or electronic or biometric security systems, to be accessible to persons other than specifically authorized employees;

(8) Keep the dispensary department securely locked and protected from entry by unauthorized employees; and

(9) Post a sign at all entry ways into any area of the dispensary facility containing marijuana, including a room with an approved safe or approved vault, which sign shall be a minimum of twelve inches in height and twelve inches in width which shall state: "Do Not Enter - Limited Access Area – Access Limited to Authorized Employees Only" in lettering no smaller than one-half inch in height.

(b) If a dispensary facility presents special security issues, such as an extremely large stock of marijuana, exposed handling or unusual vulnerability to diversion, theft or loss, the commissioner may require additional safeguards, including, but not limited to, a supervised watchman service.

(c) If diversion, theft or loss of marijuana has occurred from a dispensary facility, the commissioner shall determine the appropriate storage and security requirements for all marijuana in such dispensary facility, and may require additional safeguards to ensure the security of the marijuana.

(d) Any marijuana not stored in compliance with sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies, or stored at a location other than that for which the dispensary facility license was issued, shall be subject to embargo or seizure by the department in accordance with section 21a-96 of the Connecticut General Statutes.

(e) Any dispensary facility whose license is revoked or not renewed shall dispose of its entire stock of marijuana in accordance with sections 21a-408-64 of the Regulations of Connecticut State Agencies.

(f) If a dispensary facility has provided other safeguards which can be regarded in total

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as an adequate substitute for some element of protection required of such facility, such added protection may be taken into account by the commissioner in evaluating overall required security measures.

(Effective September 6, 2013)

Sec. 21a-408-52. Operation of production facility

- (a) Only a producer shall own and operate a production facility.
- (b) A producer shall not:
 - (1) Produce or manufacture marijuana in any place except its approved production facility;
 - (2) Sell, deliver, transport or distribute marijuana from any place except its approved production facility;
 - (3) Produce or manufacture marijuana for use outside of Connecticut;
 - (4) Sell, deliver, transport or distribute marijuana to any place except a dispensary facility located in Connecticut;
 - (5) Enter into an exclusive agreement with any dispensary facility;
 - (6) Refuse to deal with any dispensary facility that is willing to deal with such producer on the same terms and conditions as other dispensary facilities with whom the producer is dealing; or
 - (7) Either directly or indirectly discriminate in price between different dispensary facilities that are purchasing a like, grade, strain, brand, and quality of marijuana or marijuana product, provided nothing herein shall prevent differentials which only make due allowance for differences in the cost of manufacture, sale or delivery resulting from the differing methods or quantities in which such marijuana or marijuana products are sold or delivered to such dispensary facilities.
- (c) A producer license shall permit the licensee to operate at a single production facility location. Prior to operating a production facility at a different location, a producer shall obtain an additional producer license in accordance with the producer license selection and application process set forth in sections 21a-408-20 to 21a-408-21 of the Regulations of Connecticut State Agencies, except that if the maximum number of producer licenses allowed under the Act have been issued, the commissioner may permit additional production facilities to be operated by a currently licensed producer.
- (d) A producer shall establish and maintain an escrow account in a financial institution in Connecticut, obtain a letter of credit from a financial institution in Connecticut, or obtain a surety bond issued by a surety company licensed by the state of Connecticut Department of Insurance and of a capacity and rating acceptable to the commissioner, upon terms approved by the commissioner, in the amount of two million dollars. The money secured by the escrow account, letter of credit or surety bond shall be payable to the state of Connecticut in the event the producer fails to timely and successfully complete the construction of a production facility or to continue to operate such facility in a manner that provides an uninterrupted supply of marijuana or marijuana products to its usual dispensary

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facility customers during the term of the license. The commissioner may reduce or eliminate the escrow account, letter of credit or surety bond in accordance with the terms set forth in section 21a-408-29 of the Regulations of Connecticut State Agencies.

(Effective September 6, 2013)

Sec. 21a-408-53. Minimum requirements for the storage and handling of marijuana by producers

(a) All production facilities shall:

(1) Have storage areas that provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions for the production and manufacture of marijuana;

(2) Separate for storage, in a quarantined area, marijuana that is outdated, damaged, deteriorated, misbranded, or adulterated, or whose containers or packaging have been opened or breached, until such marijuana is destroyed;

(3) Be maintained in a clean and orderly condition; and

(4) Be free from infestation by insects, rodents, birds, or vermin of any kind.

(b) Any area within the production facility where marijuana will be manufactured into an edible form shall comply with the Connecticut Food, Drug and Cosmetic Act, Connecticut General Statutes, sections 21a-91 to 21a-120, inclusive, and, Connecticut General Statutes, sections 21a-151 to 21a-159, inclusive, regarding bakeries and food manufacturing establishments.

(c) A producer shall compartmentalize all areas in the production facility based on function and shall restrict access between compartments. The producer shall establish, maintain and comply with written policies and procedures, approved by the commissioner, regarding best practices for the secure and proper production and manufacturing of marijuana. These shall include, but not be limited to, policies and procedures that:

(1) Restrict movement between production compartments;

(2) Provide for different colored identification cards for production facility employees based on the production compartment to which they are assigned at a given time so as to ensure that only employees necessary for a production function have access to that compartment of the production facility;

(3) Require pocketless clothing for all production facility employees working in an area containing marijuana; and

(4) Document the chain of custody of all marijuana and marijuana products.

(d) Producers shall establish, maintain, and comply with written policies and procedures, approved by the commissioner, for the manufacture, security, storage, inventory, and distribution of marijuana. Such policies and procedures shall include methods for identifying, recording, and reporting diversion, theft or loss, and for correcting all errors and inaccuracies in inventories. Producers shall include in their written policies and procedures, a process for the following:

(1) Handling mandatory and voluntary recalls of marijuana products. Such process shall

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be adequate to deal with recalls due to any action initiated at the request of the commissioner and any voluntary action by the producer to remove defective or potentially defective marijuana products from the market or any action undertaken to promote public health and safety by replacing existing marijuana products with improved products or packaging;

(2) Preparing for, protecting against, and handling any crises that affects the security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency;

(3) Ensuring that any outdated, damaged, deteriorated, misbranded, or adulterated marijuana is segregated from all other marijuana and destroyed. This procedure shall provide for written documentation of the marijuana disposition; and

(4) Ensuring the oldest stock of a marijuana product is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate.

(e) A producer shall store all marijuana in the process of manufacture, distribution, transfer, or analysis in such a manner as to prevent diversion, theft or loss, shall make marijuana accessible only to the minimum number of specifically authorized employees essential for efficient operation, and shall return marijuana to its secure location immediately after completion of the process or at the end of the scheduled business day. If a manufacturing process cannot be completed at the end of a working day, the producer shall securely lock the processing area or tanks, vessels, bins, or bulk containers containing marijuana inside an area or building that affords adequate security.

(f) No person, except production facility employees, local law enforcement, the commissioner or commissioner's authorized representative or other federal, state of Connecticut or local government officials, where necessary to perform their governmental duties, shall be allowed on the premises of a production facility, except that:

(1) Laboratory staff may enter a production facility for the sole purpose of identifying and collecting marijuana samples for purposes of conducting laboratory tests; and

(2) Upon prior written request, the commissioner or the commissioner's authorized representative may permit other persons to enter a production facility.

(g) (1) All persons who are not production facility employees, but who are permitted on the premises of a production facility pursuant to subsection (f)(1) or (2) of this section, shall obtain a visitor identification badge from a production facility employee, prior to entering the production facility. A production facility employee shall escort and monitor visitors at all times. A visitor shall visibly display the visitor identification badge at all times the visitor is in the production facility. A visitor shall return the visitor identification badge to a production facility employee upon exiting the production facility.

(2) The producer shall log all visitors in and out, and shall maintain a log that includes the date, time and purpose of the visit. A producer shall maintain such log and make it available in accordance with section 21a-408-70 of the Regulations of Connecticut State Agencies.

(3) If an emergency requires the presence of a visitor and makes it impractical to obtain permission pursuant to subsection (f)(2) of this section, the producer shall provide written

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notice to the commissioner as soon as practicable after the onset of the emergency. Such notice shall include the name and company affiliation of the visitor, the purpose of the visit, and the date and time of the visit. A producer shall monitor the visitor and maintain a log of such visit as required by this subsection.

(Effective September 6, 2013)

Sec. 21a-408-54. Producer record keeping

Producers shall keep records of all marijuana produced or manufactured and of all marijuana disposed of by them. Such records shall be maintained and made available in accordance with section 21a-408-70 of the Regulations of Connecticut State Agencies and, in each case shall show:

- (1) The brand name, kind and quantity of marijuana involved;
- (2) The date of such production or removal from production;
- (3) A record of all marijuana sold, transported or otherwise disposed of;
- (4) The date and time of selling, transporting or disposing of the marijuana;
- (5) The name and address of the dispensary facility to which the marijuana was sold;
- (6) The name of the dispensary who took custody of the marijuana; and
- (7) The name of the production facility employee responsible for transporting the marijuana.

(Effective September 6, 2013)

Sec. 21a-408-55. Manufacturing of marijuana products

- (a) A producer shall only manufacture or sell marijuana products in the following forms:
 - (1) Raw material;
 - (2) Cigarettes;
 - (3) Extracts, sprays, tinctures or oils;
 - (4) Topical applications, oils or lotions;
 - (5) Transdermal patches;
 - (6) Baked goods; and
 - (7) Capsules or pills.
- (b) No marijuana product shall:
 - (1) Include alcoholic liquor, dietary supplements or any drug, except for pharmaceutical grade marijuana. For purposes of this provision, alcoholic liquor does not include any liquid or solid containing less than one-half of one percent of alcohol by volume or ethanol-based tinctures with an alcohol level approved by the commissioner;
 - (2) Be manufactured or sold as a beverage or confectionary;
 - (3) Be manufactured or sold in a form or with a design that:
 - (A) Is obscene or indecent;
 - (B) May encourage the use of marijuana for recreational purposes;
 - (C) May encourage the use of marijuana for a condition other than a debilitating medical condition; or

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(D) Is customarily associated with persons under the age of eighteen;
(4) Have had pesticide chemicals or organic solvents used during the production or manufacturing process, except that the commissioner may authorize the use of pesticide chemicals for purposes of addressing an infestation that could result in a catastrophic loss of marijuana crops.

(c) Any marijuana product not in compliance with this section shall be deemed adulterated.

(Effective September 6, 2013)

Sec. 21a-408-56. Packaging and labeling by producer

(a) A producer shall individually package, label and seal marijuana products in unit sizes such that no single unit contains more than a one-month supply of marijuana.

(b) A producer shall place any product containing marijuana in a child-resistant and light-resistant package. A package shall be deemed child-resistant if it satisfies the standard for “special packaging” as set forth in the Poison Prevention Packaging Act of 1970 Regulations, 16 CFR 1700.1(b)(4).

(c) A producer shall label each marijuana product prior to sale to a dispensary and shall securely affix to the package a label that states in legible English:

- (1) The name and address of the producer;
- (2) The brand name of the marijuana product that was registered with the department pursuant to section 21a-408-59 of the Regulations of Connecticut State Agencies;
- (3) A unique serial number that will match the product with a producer batch and lot number so as to facilitate any warnings or recalls the department or producer deem appropriate;
- (4) The date of final testing and packaging;
- (5) The expiration date;
- (6) The quantity of marijuana contained therein;
- (7) A terpenes profile and a list of all active ingredients, including:
 - (A) tetrahydrocannabinol (THC);
 - (B) tetrahydrocannabinol acid (THCA);
 - (C) cannabidiol (CBD);
 - (D) cannabidiolic acid (CBDA); and
 - (E) any other active ingredient that constitute at least 1% of the marijuana batch used in the product.

(8) A pass or fail rating based on the laboratory’s microbiological, mycotoxins, heavy metals and chemical residue analysis; and

(9) Such other information necessary to comply with state of Connecticut labeling requirements for similar products not containing marijuana, including but not limited to the Connecticut Food, Drug and Cosmetic Act, Connecticut General Statutes, sections 21a-91 to 21a-120, inclusive, and Connecticut General Statutes, sections 21a-151 to 21a-159, inclusive, regarding bakeries and food manufacturing establishments.

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(d) A producer shall not label marijuana products as “organic” unless the marijuana plants have been organically grown as defined in section 21a-92 of the Connecticut General Statutes and the marijuana products have been produced, processed, manufactured and certified to be consistent with organic standards in compliance with section 21a-92a of the Connecticut General Statutes.

(Effective September 6, 2013)

Sec. 21a-408-57. Laboratory requirements

No laboratory shall handle, test or analyze marijuana unless such laboratory:

- (1) Is registered with the department as a controlled substance laboratory;
- (2) Is independent from all other persons involved in the marijuana industry in Connecticut, which shall mean that no person with a direct or indirect interest in the laboratory shall have a direct or indirect financial interest in a dispensary, dispensary facility, producer, production facility, certifying physician or any other entity that may benefit from the production, manufacture, dispensing, sale, purchase or use of marijuana; and
- (3) Has employed at least one person to oversee and be responsible for the laboratory testing who has earned, from a college or university accredited by a national or regional certifying authority, at least a master’s level degree in chemical or biological sciences and a minimum of two years of post-degree laboratory experience or a bachelor’s degree in biological sciences and a minimum of four years of post-degree laboratory experience.

(Effective September 6, 2013)

Sec. 21a-408-58. Laboratory testing

(a) Immediately prior to manufacturing any marijuana product or packaging raw marijuana for sale to a dispensary, a producer shall segregate all harvested marijuana into homogenized batches.

(b) A producer shall make available each such batch at the production facility for a laboratory employee to select a random sample. The laboratory shall test each sample for microbiological contaminants, mycotoxins, heavy metals and pesticide chemical residue, and for purposes of conducting an active ingredient analysis.

(c) From the time that a batch of marijuana has been homogenized for sample testing and eventual packaging and sale to a dispensary facility, until the laboratory provides the results from its tests and analysis, the producer shall segregate and withhold from use the entire batch of marijuana, except the samples that have been removed by the laboratory for testing. During this period of segregation, the producer shall maintain the marijuana batch in a secure, cool and dry location so as to prevent the marijuana from becoming contaminated or losing its efficacy. Under no circumstances shall a producer include marijuana in a marijuana product or sell it to a dispensary facility prior to the time that the laboratory has completed its testing and analysis and provided those results, in writing, to the producer or other designated production facility employee.

(d) A laboratory shall immediately return or dispose of any marijuana upon the

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completion of any testing, use, or research. If a laboratory disposes of marijuana, the laboratory shall comply with 21a-408-64 of the Regulations of Connecticut State Agencies.

(e) If a sample of marijuana does not pass the microbiological, mycotoxin, heavy metal or pesticide chemical residue test, based on the standards set forth in this subsection, the producer shall dispose of the entire batch from which the sample was taken in accordance with section 21a-408-64 of the Regulations of Connecticut State Agencies.

(1) For purposes of the microbiological test, a marijuana sample shall be deemed to have passed if it satisfies the standards set forth in Section 1111 of the United States Pharmacopeia, which can be obtained at <http://www.usp.org>.

(2) For purposes of the mycotoxin test, a marijuana sample shall be deemed to have passed if it meets the following standards:

Test	Specification
Alfatoxin B1	<20 uG/KG of Substance
Alfatoxin B2	<20 uG/KG of Substance
Alfatoxin O1	<20 uG/KG of Substance
Alfatoxin O2	<20 uG/KG of Substance
Ochratoxin A	<20 uG/KG of Substance

(3) For purposes of the heavy metal test, a marijuana sample shall be deemed to have passed if it meets the following standards:

Metal	Natural Health Products Acceptable limits uG/KG BW/Day
Arsenic	<0.14
Cadmium	<0.09
Lead	<0.29
Mercury	<0.29

(4) For purposes of the pesticide chemical residue test, a marijuana sample shall be deemed to have passed if it satisfies the most stringent acceptable standard for a pesticide chemical residue in any food item as set forth in Subpart C of the federal Environmental Protection Agency's regulations for Tolerances and Exemptions for Pesticide Chemical Residues in Food, 40 CFR 180.

(f) If a sample of marijuana passes the microbiological, mycotoxin, heavy metal and pesticide chemical residue test, the laboratory shall release the entire batch for immediate manufacturing, packaging and labeling for sale to a dispensary facility.

(g) The laboratory shall file with the department an electronic copy of each laboratory test result for any batch that does not pass the microbiological, mycotoxin, heavy metal or pesticide chemical residue test, at the same time that it transmits those results to the

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producer. In addition, the laboratory shall maintain the laboratory test results and make them available in accordance with section 21a-408-70 of the Regulations of Connecticut State Agencies.

(h) A producer shall provide to a dispensary facility the laboratory test results for each batch of marijuana used in a product purchased by the dispensary facility. Each dispensary facility shall have such laboratory results available upon request to qualifying patients, primary caregivers and physicians who have certified qualifying patients.

(Effective September 6, 2013)

Sec. 21a-408-59. Brand name

(a) A producer shall assign a brand name to each marijuana product. A producer shall register each brand name with the department, on a form prescribed by the commissioner, prior to any sale to a dispensary facility and shall associate each brand name with a specific laboratory test that includes a terpenes profile and a list of all active ingredients, including:

- (1) Tetrahydrocannabinol (THC);
- (2) Tetrahydrocannabinol acid (THCA);
- (3) Cannabidiols (CBD);
- (4) Cannabidiolic acid (CBDA); and
- (5) Any other active ingredient that constitutes at least 1% of the marijuana batch used in the product.

(b) A producer shall not label two marijuana products with the same brand name unless the laboratory test results for each product indicate that they contain the same level of each active ingredient listed within subsection (a)(1) to (4), inclusive, of this section within a range of 97% to 103%.

(c) The department shall not register any brand name that:

- (1) Is identical to, or confusingly similar to, the name of an existing non-marijuana product;
- (2) Is identical to, or confusingly similar to, the name of an unlawful product or substance;
- (3) Is confusingly similar to the name of a previously approved marijuana product brand name;
- (4) Is obscene or indecent;
- (5) May encourage the use of marijuana for recreational purposes;
- (6) May encourage the use of marijuana for a condition other than a debilitating medical condition;
- (7) Is customarily associated with persons under the age of 18; or
- (8) Is related to the benefits, safety or efficacy of the marijuana product unless supported by substantial evidence or substantial clinical data.

(Effective September 6, 2013)

Sec. 21a-408-60. Transportation of marijuana

- (a) Prior to transporting any marijuana or marijuana product, a producer shall:
- (1) Complete a shipping manifest using a form prescribed by the commissioner; and
 - (2) Securely transmit a copy of the manifest to the dispensary facility that will receive the products and to the department at least twenty-four hours prior to transport.
- (b) The producer and dispensary facility shall maintain all shipping manifests and make them available in accordance with section 21a-408-70 of the Regulations of Connecticut State Agencies.
- (c) A producer shall only transport marijuana products:
- (1) In a locked, safe and secure storage compartment that is part of the vehicle transporting the marijuana; and
 - (2) In a storage compartment that is not visible from outside the vehicle.
- (d) A production facility employee, when transporting marijuana, shall travel directly from the producer facility to the dispensary facility and shall not make any stops in between, except to other dispensary facilities.
- (e) A producer shall ensure that all delivery times and routes are randomized.
- (f) A producer shall staff all transport vehicles with a minimum of two employees. At least one delivery team member shall remain with the vehicle at all times that the vehicle contains marijuana.
- (g) A delivery team member shall have access to a secure form of communication with employees at the production facility at all times that the vehicle contains marijuana.
- (h) A delivery team member shall possess a department-issued identification card at all times when transporting or delivering marijuana and shall produce it to the commissioner, the commissioner's authorized representative or law enforcement official upon request.

(Effective September 6, 2013)

Sec. 21a-408-61. Security requirements for producers

- (a) A producer shall:
- (1) Not produce, manufacture or maintain marijuana in excess of the quantity required for normal, efficient operation;
 - (2) Store all marijuana products in an approved safe or approved vault and in such a manner as to prevent diversion, theft or loss;
 - (3) Maintain all marijuana that is not part of a finished product in a secure area or location within the production facility accessible only to specifically authorized employees, which shall include only the minimum number of employees essential for efficient operation;
 - (4) Keep all approved safes, approved vaults, or any other approved equipment or areas used for the production, cultivation, harvesting, processing, manufacturing or storage of marijuana, securely locked or protected from entry, except for the actual time required to remove or replace marijuana;
 - (5) Keep all locks and security equipment in good working order;
 - (6) Not allow keys to be left in the locks and not store or place keys in a location

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accessible to persons other than specifically authorized employees;

(7) Not allow other security measures, such as combination numbers, passwords or electronic or biometric security systems, to be accessible to persons other than specifically authorized employees; and

(8) Keep the production facility securely locked and protected from entry at all times.

(b) If a production facility presents special security issues, such as an extremely large stock of marijuana, exposed handling or unusual vulnerability to diversion, theft or loss, the commissioner may require additional safeguards such as a supervised watchman service.

(c) If a loss, theft, or diversion of marijuana has occurred from a production facility, the commissioner shall determine the appropriate storage and security requirements for all marijuana in such production facility, and may require additional safeguards to ensure the security of the marijuana.

(d) Any marijuana not stored in compliance with sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies, or at a location other than that for which the producer license was issued, shall be subject to seizure in accordance with section 21a-96 of the Connecticut General Statutes.

(e) Any producer whose license is revoked or not renewed shall dispose of its entire stock of marijuana under conditions approved by the department.

(f) If a producer has provided other safeguards, which can be regarded in total as an adequate substitute for some element of protection required of such producer, such added protection may be taken into account by the commissioner in evaluating overall required security measures.

(g) No person shall be allowed access to any area within a production facility containing marijuana except laboratory employees and production facility employees whose responsibilities necessitate access to the area of the production facility containing marijuana and then for only as long as necessary to perform the person's job duties.

(h) Any area of a production facility containing marijuana, including a room with an approved safe or approved vault, shall have a sign posted at all entry ways, which shall be a minimum of twelve inches in height and twelve inches in width and shall state: "Do Not Enter - Limited Access Area – Access Limited to Authorized Employees Only" in lettering no smaller than one-half inch in height.

(i) Notwithstanding the requirements of sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies, members of the department, local law enforcement or other federal, state of Connecticut or local government officials may enter any area of a production facility if necessary to perform their governmental duties.

(Effective September 6, 2013)

Sec. 21a-408-62. Security alarm systems; minimum requirements for dispensary facilities and production facilities

(a) All dispensary facilities and production facilities shall have an adequate security system to prevent and detect diversion, theft or loss of marijuana utilizing commercial grade

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equipment, which shall, at a minimum, include:

- (1) A perimeter alarm;
- (2) Motion detector;
- (3) Video cameras in all areas that may contain marijuana and at all points of entry and exit, which shall be appropriate for the normal lighting conditions of the area under surveillance. The dispensary facility or production facility shall direct cameras at all approved safes, approved vaults, dispensing areas, marijuana sales areas and any other area where marijuana is being produced, harvested, manufactured, stored or handled. At entry and exit points, the dispensary facility or production facility shall angle cameras so as to allow for the capture of clear and certain identification of any person entering or exiting the facility;
- (4) Twenty-four hour recordings from all video cameras, which the dispensary facility or production facility shall make available for immediate viewing by the commissioner or the commissioner's authorized representative upon request and shall retain for at least thirty days. If a dispensary facility or producer is aware of a pending criminal, civil or administrative investigation or legal proceeding for which a recording may contain relevant information, the dispensary facility or producer shall retain an unaltered copy of the recording until the investigation or proceeding is closed or the entity conducting the investigation or proceeding notifies the dispensary facility manager or producer that it is not necessary to retain the recording;
- (5) Duress alarm, which for purposes of this subsection means a silent security alarm system signal generated by the entry of a designated code into an arming station in order to signal that the alarm user is being forced to turn off the system;
- (6) Panic alarm, which for purposes of this subsection means an audible security alarm system signal generated by the manual activation of a device intended to signal a life threatening or emergency situation requiring a law enforcement response;
- (7) Holdup alarm, which for purposes of this subsection means a silent alarm signal generated by the manual activation of a device intended to signal a robbery in progress;
- (8) Automatic voice dialer, which for purposes of this subsection means any electrical, electronic, mechanical, or other device capable of being programmed to send a prerecorded voice message, when activated, over a telephone line, radio or other communication system, to a law enforcement, public safety or emergency services agency requesting dispatch;
- (9) A failure notification system that provides an audible, text or visual notification of any failure in the surveillance system. The failure notification system shall provide an alert to the dispensary facility or producer within five minutes of the failure, either by telephone, email, or text message;
- (10) The ability to immediately produce a clear color still photo that is a minimum of 9600 dpi from any camera image (live or recorded);
- (11) A date and time stamp embedded on all recordings. The date and time shall be synchronized and set correctly and shall not significantly obscure the picture; and
- (12) The ability to remain operational during a power outage.

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(b) A dispensary facility or a production facility shall maintain all security system equipment and recordings in a secure location so as to prevent theft, loss, destruction or alterations.

(c) In addition to the requirements listed in subsection (a) of this section, each production facility shall have a back-up alarm system approved by the commissioner that shall detect unauthorized entry during times when no employees are present at the facility and that shall be provided by a company supplying commercial grade equipment, which shall not be the same company supplying the primary security system.

(d) A dispensary facility or a production facility shall limit access to surveillance areas to persons that are essential to surveillance operations, law enforcement agencies, security system service employees, the commissioner or the commissioner's authorized representative, and others when approved by the commissioner. A dispensary facility and producer shall make available a current list of authorized employees and service employees that have access to the surveillance room to the commissioner or the commissioner's authorized representative upon request. A dispensary facility and producer shall keep all on-site surveillance rooms locked and shall not use such rooms for any other function.

(e) A dispensary facility and producer shall keep the outside perimeter of the dispensary facility and production facility premises well-lit.

(f) All video recording shall allow for the exporting of still images in an industry standard image format, including .jpg, .bmp, and .gif. Exported video shall have the ability to be archived in a proprietary format that ensures authentication of the video and guarantees that no alteration of the recorded image has taken place. Exported video shall also have the ability to be saved in an industry standard file format that can be played on a standard computer operating system. A dispensary facility and producer shall erase all recordings prior to disposal or sale of the facility.

(g) A dispensary facility and producer shall keep all security equipment in good-working order and shall test such equipment no less than two times per year.

(Effective September 6, 2013)

Sec. 21a-408-63. Dispensary and producer reportable events

(a) Upon becoming aware of discrepancies identified during inventory, diversion, theft, loss, or unauthorized destruction of any marijuana or of any loss or unauthorized alteration of records related to marijuana or qualifying patients, a dispensary or producer shall immediately notify:

- (1) Appropriate law enforcement authorities; and
- (2) The Drug Control Division of the department.

(b) A dispensary or producer shall provide the notice required by subsection (a) of this section to the department by way of a signed statement which details the circumstances of the event, including an accurate inventory of the quantity and brand names of marijuana diverted, stolen, lost, destroyed or damaged and confirmation that the local law enforcement authorities were notified. A dispensary or producer shall make such notice no later than

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twenty-four hours after discovery of the event.

(c) A dispensary or producer shall notify the Drug Control Division of the department no later than the next business day, followed by written notification no later than ten business days, of any of the following:

- (1) An alarm activation or other event that requires response by public safety personnel;
- (2) A breach of security;
- (3) The failure of the security alarm system due to a loss of electrical support or mechanical malfunction that is expected to last longer than eight hours; and
- (4) Corrective measures taken, if any.

(d) A dispensary and producer shall maintain and shall make available all documentation related to an occurrence that is reportable pursuant to subsections (a) through (c), inclusive, of this section in accordance with section 21a-408-70 of the Regulations of Connecticut State Agencies.

(Effective September 6, 2013)

Sec. 21a-408-64. Disposal of marijuana

(a) A dispensary, producer, laboratory, law enforcement or court official or the commissioner or the commissioner's authorized representative shall dispose of undesired, excess, unauthorized, obsolete, adulterated, misbranded or deteriorated marijuana in the following manner:

- (1) By surrender without compensation of such marijuana to the commissioner or the commissioner's authorized representative; or
- (2) By disposal in the presence of an authorized representative of the commissioner in such a manner as to render the marijuana non-recoverable.

(b) The person disposing of the marijuana shall maintain and make available in accordance with section 21a-408-70 of the Regulations of Connecticut State Agencies a separate record of each such disposal indicating:

- (1) The date and time of disposal;
- (2) The manner of disposal;
- (3) The brand name and quantity of marijuana disposed of; and
- (4) The signatures of the persons disposing of the marijuana, the authorized representative of the commissioner and any other persons present during the disposal.

(Effective September 6, 2013)

Sec. 21a-408-65. Inventory

(a) Each dispensary facility and production facility, prior to commencing business, shall:

- (1) Conduct an initial comprehensive inventory of all marijuana at the facility. If a facility commences business with no marijuana on hand, the dispensary or producer shall record this fact as the initial inventory; and
- (2) Establish ongoing inventory controls and procedures for the conduct of inventory reviews and comprehensive inventories of marijuana, which shall enable the facility to

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detect any diversion, theft or loss in a timely manner.

(b) Upon commencing business, each dispensary facility and production facility shall conduct a weekly inventory of marijuana stock, which shall include, at a minimum, the date of the inventory, a summary of the inventory findings, the name, signature and title of the individuals who conducted the inventory, the date of receipt of marijuana, the name and address of the producer from whom received, where applicable, and the kind and quantity of marijuana received. The record of all marijuana sold, dispensed or otherwise disposed of shall show the date of sale, the name of the dispensary facility, qualifying patient or primary caregiver to whom the marijuana was sold, the address of such person and the brand and quantity of marijuana sold.

(c) A complete and accurate record of all stocks or brands of marijuana on hand shall be prepared annually on the anniversary of the initial inventory or such other date that the dispensary facility manager or producer may choose, so long as it is not more than one year following the prior year's inventory.

(d) All inventories, procedures and other documents required by this section shall be maintained on the premises and made available in accordance with section 21a-408-70 of the Regulations of Connecticut State Agencies.

(e) Whenever any sample or record is removed by a person authorized to enforce the provisions of sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies or the provisions of the state of Connecticut food, drug and cosmetic statutes and regulations for the purpose of investigation or as evidence, such person shall tender a receipt in lieu thereof and the receipt shall be kept for a period of at least three years.

(Effective September 6, 2013)

Sec. 21a-408-66. Marketing: prohibited conduct, statements and illustrations; commissioner review of advertisements

(a) A producer, production facility employee, producer backer, dispensary facility employee, dispensary facility backer or physician, in any combination, shall not cooperate, directly or indirectly, in any advertising if such advertising has the purpose or effect of steering or influencing patient or caregiver choice with regard to the selection of a physician, dispensary or marijuana product.

(b) An advertisement for marijuana or any marijuana product shall not contain:

(1) Any statement that is false or misleading in any material particular or is otherwise in violation of the Connecticut Unfair Trade Practices Act, sections 42-110a to 42-110q, inclusive, of the Connecticut General Statutes;

(2) Any statement that falsely disparages a competitor's products;

(3) Any statement, design, or representation, picture or illustration that is obscene or indecent;

(4) Any statement, design, representation, picture or illustration that encourages or represents the use of marijuana for a condition other than a debilitating medical condition;

(5) Any statement, design, representation, picture or illustration that encourages or

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represents the recreational use of marijuana;

(6) Any statement, design, representation, picture or illustration related to the safety or efficacy of marijuana, unless supported by substantial evidence or substantial clinical data;

(7) Any statement, design, representation, picture or illustration portraying anyone under the age of eighteen, objects suggestive of the presence of anyone under the age of eighteen, or containing the use of a figure, symbol or language that is customarily associated with anyone under the age of eighteen;

(8) Any offer of a prize, award or inducement to a qualifying patient, primary caregiver or physician related to the purchase of marijuana or a certification for the use of marijuana; or

(9) Any statement that indicates or implies that the product or entity in the advertisement has been approved or endorsed by the commissioner, department, the state of Connecticut or any person or entity associated with the state of Connecticut.

(c) Any advertisement for marijuana or a marijuana product shall be submitted to the commissioner at the same time as, or prior to, the dissemination of the advertisement.

(d) The submitter of the advertisement shall provide the following information in addition to the advertisement itself:

(1) A cover letter that:

(A) Provides the following subject line: Medical marijuana advertisement review package for a proposed advertisement for (Brand Name);

(B) Provides a brief description of the format and expected distribution of the proposed advertisement; and

(C) Provides the submitter's name, title, address, telephone number, fax number, and email address;

(2) An annotated summary of the proposed advertisement showing every claim being made in the advertisement and which references support for each claim;

(3) Verification that a person identified in an advertisement as an actual patient or health care practitioner is an actual patient or health care practitioner and not a model or actor;

(4) Verification that a spokesperson who is represented as an actual patient is indeed an actual patient;

(5) Verification that an official translation of a foreign language advertisement is accurate;

(6) Annotated references to support disease or epidemiology information, cross-referenced to the advertisement summary; and

(7) A final copy of the advertisement, including a video where applicable, in a format acceptable to the commissioner.

(e) Advertising packages that are missing any of the elements in subsection (d) of this section, or that fail to follow the specific instructions for submissions, shall be considered incomplete. If the department receives an incomplete package, it shall so notify the submitter.

(f) The commissioner may:

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(1) Require a specific disclosure be made in the advertisement in a clear and conspicuous manner if the commissioner determines that the advertisement would be false or misleading without such a disclosure; or

(2) Make recommendations with respect to changes that are:

(A) Necessary to protect the public health, safety and welfare; or

(B) Consistent with dispensing information for the product under review.

(3) If appropriate and if information exists, recommend statements for inclusion in the advertisement to address the specific efficacy of the drug as it relates to specific disease states, disease symptoms and population groups.

(Effective September 6, 2013)

Sec. 21a-408-67. Marijuana advertising; requirements for true statements and fair balance

(a) All advertisements for marijuana or marijuana products that make a statement relating to side effects consequences, contraindications and effectiveness shall present a true statement of such information. When applicable, advertisements broadcast through media such as radio, television, or other electronic media shall include such information in the audio or audio and visual parts of the presentation.

(b) False or misleading information in any part of the advertisement shall not be corrected by the inclusion of a true statement in another distinct part of the advertisement.

(c) An advertisement does not satisfy the requirement that it present a “true statement” of information relating to side effects, consequences, contraindications, and effectiveness if it fails to present a fair balance between information relating to side effects, consequences, contraindications and effectiveness in that the information relating to effectiveness is presented in greater scope, depth, or detail than is the information relating to side effects, consequences and contraindications, taking into account all implementing factors such as typography, layout, contrast, headlines, paragraphing, white space, and any other techniques apt to achieve emphasis.

(d) An advertisement is false, lacking in fair balance, or otherwise misleading if it:

(1) Contains a representation or suggestion that a marijuana strain, brand or product is better, more effective, useful in a broader range of conditions or patients or safer than other drugs or treatments including other marijuana strains or products, unless such a claim has been demonstrated by substantial evidence or substantial clinical experience;

(2) Contains favorable information or opinions about a marijuana product previously regarded as valid but which have been rendered invalid by contrary and more credible recent information;

(3) Uses a quote or paraphrase out of context or without citing conflicting information from the same source, to convey a false or misleading idea;

(4) Uses a study on individuals without a debilitating medical condition without disclosing that the subjects were not suffering from a debilitating medical condition;

(5) Uses data favorable to a marijuana product derived from patients treated with a

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different product or dosages different from those approved in the state of Connecticut;

(6) Contains favorable information or conclusions from a study that is inadequate in design, scope, or conduct to furnish significant support for such information or conclusions; or

(7) Fails to provide adequate emphasis for the fact that two or more facing pages are part of the same advertisement when only one page contains information relating to side effects, consequences and contraindications.

(e) No advertisement may be disseminated if the submitter of the advertisement has received information that has not been widely publicized in medical literature that the use of the marijuana product or strain may cause fatalities or serious damage to a patient.

(Effective September 6, 2013)

Sec. 21a-408-68. Marijuana marketing; advertising at a dispensary facility; producer advertising of prices

(a) A dispensary facility shall:

(1) Except as otherwise provided in sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies, restrict external signage to a single sign no larger than sixteen inches in height by eighteen inches in width;

(2) Not illuminate a dispensary facility sign advertising a marijuana product at any time;

(3) Not advertise marijuana brand names or utilize graphics related to marijuana or paraphernalia on the exterior of the dispensary facility or the building in which the dispensary facility is located; and

(4) Not display marijuana and paraphernalia so as to be clearly visible from the exterior of a dispensary facility.

(b) A producer shall not advertise the price of its marijuana, except that it may make a price list available to a dispensary facility.

(Effective September 6, 2013)

Sec. 21a-408-69. Dispensary facility and producer records; furnishing of information; audits

(a) Each dispensary facility and producer shall maintain a complete set of all records necessary to fully show the business transactions related to marijuana for a period of the current tax year and the three immediately prior tax years, all of which shall be made available in accordance with section 21a-408-70 of the Regulations of Connecticut State Agencies.

(b) The commissioner may require any licensee or registrant to furnish such information as the commissioner considers necessary for the proper administration of the Act and sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies, and may require an audit of the business of any dispensary facility or producer and the expense thereof shall be paid by such dispensary facility or producer.

(Effective September 6, 2013)

Sec. 21a-408-70. Inspection of records; entry on premises

(a) Every person required by sections 21a-408-1 to 21a-408-69, inclusive, of the Regulations of Connecticut State Agencies, to prepare, obtain or keep records, logs, reports or other documents, and every person in charge, or having custody, of such documents, shall maintain such documents in an auditable format for no less than three years. Upon request, such person shall make such documents immediately available for inspection and copying by the commissioner, the commissioner's authorized representative or others authorized by the Act or sections 21a-408-1 to 21a-408-69, inclusive, of the Regulations of Connecticut State Agencies, to review the documents. In complying with this section, no person shall use a foreign language, codes or symbols to designate marijuana types or persons in the keeping of any required document.

(b) For purposes of the supervision and enforcement of the medical marijuana program established pursuant to chapter 420f of the Connecticut General Statutes, the commissioner or the commissioner's authorized representative, is authorized:

(1) To enter, at reasonable times, any place, including a vehicle, in which marijuana is held, dispensed, sold, produced, delivered, transported, manufactured or otherwise disposed of;

(2) To inspect within reasonable limits and in a reasonable manner, such place and all pertinent equipment, finished and unfinished material, containers and labeling, and all things therein including records, files, financial data, sales data, shipping data, pricing data, employee data, research, papers, processes, controls and facilities; and

(3) To inventory any stock of marijuana therein and obtain samples of any marijuana or marijuana product, any labels or containers for marijuana, paraphernalia, and of any finished and unfinished material.

(Effective September 6, 2013)