Agency
Department of Consumer Protection
Subject
Connecticut Food, Drug and Cosmetic Act
Inclusive Sections
§§ 21a-115-1—21a-115-77

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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

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,

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

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 hes 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

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 promit 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-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

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

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

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 sulphurus acid is prohibited. The use of any of the nitrates or nitrites listed

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 $^{1}/_{10}$ of 1 per cent; or (B) nordihydroguaiaretic acid not to exceed $^{1}/_{100}$ of 1 per cent; or (C) tocopherols not to exceed $^{3}/_{100}$ of 1 per cent; or (D) lecithin; or (E) citric acid not to exceed $^{1}/_{100}$ of 1 per cent; or (F) citric or phosphoric acid not to exceed $^{5}/_{1000}$ of 1 per cent, in combination with not more than $^{1}/_{100}$ of 1 per cent of nordihydroguaiaretic acid; or (G) propyl gallate not to exceed $^{1}/_{100}$ of 1 per cent; or (H) propyl gallate not to exceed $^{1}/_{100}$ of 1 per cent in combination with not more than $^{5}/_{1000}$ of 1 per cent of citric acid; or (I) thiodipropionic acid, dilauryl thiodipropionate, distearyl thiodipropionate or combinations thereof in quantities not to exceed $^{1}/_{100}$ of 1 per cent of thiodipropionic acid and $^{9}/_{100}$ 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 nordidydroguaiaretic acid or propyl gallate with or without the addition of citric or phosphoric acid, in quantities not to exceed $^{2}/_{100}$ of 1 per cent of butylated hydroxyanisole, or $^{1}/_{100}$ of 1 per cent of nordihydroguaiaretic acid plus $^{2}/_{100}$ of 1 per cent of butylated hydroxyanisole, or $^{1}/_{100}$ of 1 per cent propyl gallate plus $^{2}/_{100}$ of 1 per cent of butylated hydroxyanisole. Citric or phosphoric acid, not to exceed $^{5}/_{1000}$ of 1 per cent, may be added with any of these.

(n) **Labeling of unpaged 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.

(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

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 forin 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

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

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

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

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 . . . . . ," "Retailed 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

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

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

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

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 "acetophenetidin" 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

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, hyoscine or hyoscyamine contained in such drug, if such alkaloid is contained therein as a constituent of belladonna, hyoscyamus, scopola, 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,

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

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

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 sement 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

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 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 sudivision (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.

(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

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

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

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

§Olive Oil	4 oz.	⅛
§Olive Oil	8 oz.	¼
§Olive Oil	32 oz.	¼
Oyster Cocktail Sauce	½ lb.	⅛
Paprika	2 oz.	⅛
Peaches	No. 3	1
Peanut Butter	—	½
Pears	No. 2	½
Pears	No. 3	1
Peas	No. 2	½
Peas, Split	1 lb.	½
Peppers	No. 1	½
Peppers	No. 2	1
Pickles, Sweet	—	½
Pickles, Relish	—	½
Pineapple	No. 2	1
Plums	No. 2	½
Pork and Beans	No. 2	½
Porter	Qt.	½
Porter	Pt.	¼
Preserves	—	½
Pumpkins	No. 3	½

‡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

(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

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, markted, 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.**

(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

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

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

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)

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)

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)