

**Sec. 21a-115-17. Labeling of drugs and devices; information re manufacturer, packer or distributor; statement of quantity**

(a) If a drug or device is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase which reveals the connection such person has with such drug or device, such as "Manufactured for and Packed by . . . . .," "Distributed by . . . . .," "Retailled by . . . . .," or other similar word or phrase which expresses the facts.

(b) The statement of the place of business shall include the street address, if any, of such place, unless such street address is shown in a current city directory or telephone directory.

(c) Where a person manufactures, packs or distributes a drug or device at a place other than his principal place of business, the label may state the principal place of business in lieu of the actual place where each package of such drug or device was manufactured or packed or is to be distributed, if such statement is not misleading in any particular.

(d) The requirement that the label shall contain the name and place of business of the manufacturer, packer or distributor shall not be considered to relieve any drug or device from the requirement that its label shall not be misleading in any particular.

(e) (1) The statement of the quantity of the contents of a package of a drug shall reveal the quantity of such drug in the package, exclusive of wrappers and other material packed with such drug. (2) The statement shall be expressed in the terms of weight, measure or numerical count, or a combination of numerical count and weight or measure, which are generally used by consumers and users of such drug to express quantity thereof and which give accurate information as to such quantity. But if no general usage in expressing accurate information as to the quantity of such drug exists among consumers and users thereof, the statement of the quantity of a drug which is not in tablet, capsule, ampul or other unit form shall be in terms of weight if the drug is solid, semi-solid or viscous, or in terms of measure if the drug is liquid; the statement of the quantity of a drug which is in such unit form shall be in terms of the numerical count of such units, supplemented, when necessary to give accurate information as to the quantity of such drug in the package, by such statement, in such terms, manner and form as are not misleading, of the weight or measure of such units, or of the quantity of each active ingredient in each such unit, as will give such information. (3) The statement of the quantity of a device shall be expressed in terms of numerical count.

(f) A statement of weight shall be in terms of the avoirdupois pound, ounce and grain, or of the kilogram, gram and milligram. A statement of liquid measure shall be in terms of the United States gallon of two hundred thirty-one cubic inches and quart, pint, fluid ounce and fluid dram subdivisions thereof, or of the liter, milliliter or cubic centimeter, and shall express the volume at 68°F. (20°C.).

(g) Statements of the quantity of a drug shall contain only such fractions as are generally used in expressing the quantity of such drug. A common fraction shall be reduced to its 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

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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)