CPG Sec. 140.500 Metric Declarations of Quantity of Contents on Product Labels

BACKGROUND:

The Metric Conversion Act of 1975 (80 stat 1007) was enacted to voluntarily increase the use of the metric system of weights and measures in the United States. In support of this policy, the agency has developed the following guidance on the use of the metric system in declaring the net quantity of contents on the labels of FDA-regulated commodities.

This guide establishes general and specific guidance for the voluntary use of metric units of quantity to state the net quantity of contents on the labeling, including the principal display panel, of an FDA-regulated commodity.

POLICY:

1. A metric declaration of quantity of contents is not considered to be "other printed label information" that would be subject to the separation requirements of 21 CFR 101.105(f), 201.62(e), 501.105(f), 701.13(f), and 801.62(e).
2. On packages of foods labeled in English, with an alternate principal display panel in a foreign language, FDA does not object to the foreign language panel bearing only a metric declaration of net contents. This assumes, of course, that the container labeling otherwise complies fully with the Federal Food, Drug, and Cosmetic Act, the Fair Packaging and Labeling Act, and the regulations promulgated thereunder.
3. Labeling requirements for over-the-counter drugs (21 CFR 201.62(l)) provide for use of the "mcg", "l", "ml", "cm^3" symbols instead of the "ug", "L". "mL" and "cm^3" symbols recommended in this guide. However, FDA will not take regulatory action if a label for an over-the-counter drug bears the symbols recommended in this guide, rather than the symbols stated in 21 CFR 201.62(l).

SUPPLEMENTAL GUIDANCE:

The principles suggested here do not convey legal requirements, but those preparing labeling may rely on these principles as acceptable to FDA.

1. Definitions

   A. Metric system - The International System of Units (from the French "Le Systeme International d'Unites"), as modified for use in the United States by the Secretary of Commerce . The acrony "SI" is used to refer to this metric system. A lisit of SI units appropiate for declarations of quantity of contents appears in section B. A complete list of SI units and other information concerning the metric system can be found in Federal Standard 376A. This standard can be purchased from the General Services Administration, Specification Unit (WFSIS), 7th and D Streets, S.W., Room 6039, Washington D.C. 20407. Also helpful in using the metric system is the Metric Editorial Guide, 4th edition, by the American National Metric Council, 1010 Vermont Avenue, N.W., Suite 320, Washington, D.C. 20015.

   B. Inch-pound units - Units based upon the yard and the pound commonly used in the United States and defined by the National *Institute for* Standards *Technology.* (Units having the same names in other countries may differ in magnitude).

2. SI Unit Prefixes

   A. The following chart (excerpted from the Metric Editorial Guide) indicates SI unit prefixes that may be used on a broad range of consumer commodity labels:

   SI UNIT PREFIXES

   Multiplication

   Factor Prefix Symbol Term (USA)

   10^{18} exa E one quintillion

   10^{15} peta P one quadrillion

   10^{12} tera T one trillion

   10^{9} giga G one billion

   10^{6} mega M one million

   10^{3} kilo k one thousand

   10^{2} hecto h one hundred

   10 deka da ten

   10^{-1} deci d one tenth

   10^{-2} centi c one hundreth

   10^{-3} milli m one thousandth

   10^{-6} micro u one millionth

   10^{-9} nano n one billionth

   10^{-12} pico p one trillionth

10^{-15} femto f one quadrillionth

10^{-18} atto a one quintillionth

B. In symbols or names for units having prefixes, no space is left between letters making up the symbol or the name.

Examples: mL, milliliter; mm, millimeter

C. Prefixes chosen should result in

(1) numerical values between 0.1 and 1000, and

(2) decimal fractions of no more than two places.

3. Units

A. Unless FDA advises otherwise, a declaration of quantity of contents:

(1) In units of weight, is expressed in terms of the kilogram, gram, milligram, or microgram.

(2) In units of liquid measure, is expressed in terms of the liter or milliliter at 20 ^{o}C, except for:

- petroleum products, the declaration expresses the volume at 15^{o}C,
- a commodity that is normally sold and consumed while frozen, the declaration expresses the volume at the frozen temperature, and
- a commodity that is normally sold in the refrigerated state, the declaration expresses the volume at 4 ^{o}C.

(3) In units of linear measure, is expressed in terms of the meter, centimeter, or millimeter.

(4) In units of area measure, is expressed in terms of the square meter or square centimeter.

(5) In units of volume other than liquid measure, is expressed in terms of the liter and milliliter, except that the terms cubic meter and cubic centimeter are used only when specifically designated as a method of sale.

B. A number of foreign countries use "re" rather than "er" spellings for the ending of metric units of measure (e.g., metre, litre, etc.). The "er" spellings are preferred for all products sold in the U.S. FDA suggests that firms using "re" spellings revise their labels to contain "er" spellings as their labels are reprinted.

C. Unit names, including prefixes, are not capitalized except at the beginning of a sentence and in titles, headings, and other instances in which all main words are capitalized.

D. A space is left between a numeral and the unit name or symbol to which it refers.

Examples: 22 mg, 22 mL

E. The decimal marker is a dot on the line. (This is the practice in the United States and Canada; however, many countries use a comma or a raised dot).

F. Decimal notation is preferred with metric measurements, but simple fractions are acceptable, such as those where the denominator is 2, 4, and 8. A fraction should be reduced to its lowest terms.

G. A zero before the decimal point should be used in numbers between 1 and - 1 to prevent the possibility that a faint decimal point will be overlooked.

Example: The oral expression "point seven five" is written 0.75

4. Symbols

A. The following symbols for metric units are used in the declaration of quantity:

kilogram kg meter m
gram g centimeter cm
milligram mg millimeter mm
microgram ug square meter m^2
liter L square centimeter cm^2
milliter mL cubic meter m^3cubic centimeter cm^3

B. Symbols, except for liter, are not capitalized unless the unit is derived from a proper name. Periods should not be used after the symbol. Symbols for units are the same in singular and plural.

Example: 1 m, 100 m

C. The "L" symbol for liter and "mL" symbol for millileter are preferred. FDA suggests that firms using "l" and "ml"symbols revise their labels to contain "L" and "mL" symbols as their labels are reprinted.

5. Calculations

A. Conversion - The following conversion factors should be used to determine metric equivalents from inch-pound units (factors are excerpted from Federal Standard 376A):

Length

Convert To Multiplied by:

inch meter(m) 0.025 4

foot meter(m) 0.304 8

yard meter(m) 0.914 4

Area

Convert To Multiplied by:

sq inch centimeter^2 (cm^2) 6.451 6

sq foot meter^2 (m^2) 0.092 903 04

sq yard meter^2 (m^2) 0.836 127 4

Volume

Convert To Multiplied by:

fluid oz liter (L) 0.029 573 53

pt (liquid) liter (L) 0.473 176 5

qt (liquid) liter (L) 0.946 352 9

gal (liquid) liter (L) 3.785 412

cubic foot liter (L) 28.31 6 85

bushel liter (L) 35.23 9 07

Mass(weight)

Convert To Multiplied by:

grain milligram (mg) 64.798 91

ounce (avoirdupois) kilogram(kg) 0.028 349 52

pound (avoirdupois) kilogram(kg) 0.453 592 37

B. Rounding - When the digits to be discarded begin with a 5 or more, increase by one unit the last digit retained.

Example: 8.3745, if rounded to three digits, would be 8.37; 8.3745, if rounded to four digits, would be 8.375

C. Significant digits - Consider significant digits when converting and rounding inch-pound units to metric units. Significant digits as defined by the American Heritage Dictionary are "digits of the decimal form of a number beginning with the leftmost nonzero digit and extending to the right to include all digits warranted by the accuracy of measuring devices used to obtain the numbers." Although zero digits at the beginning of a number (e.g., 0.1, 0.01) are never significant digits, zero digits at the end of a number (e.g., 0.10, 10, 10 000) may be significant digits if the digit is known to be reasonably reliable. The Metric Editorial Guide advises that "Zeros at the end of a number are not considered significant unless their use results in a number that is closer to the true value than would be the case if the number were increased or decreased by 1." The position of a decimal point in a number does not affect the number of significant digits in that number (e.g., the number 2834, 28.34, and 0.002 834 all have four significant digits.

The Metric Editorial Guide provides the following rules concerning significant digits:

(1) If the first significant digit of the metric value is EQUAL TO OR LARGER than the first significant digit of the inch-pound value, round the metric value to the SAME NUMBER of significant digits as there are in the inch-pound value.

Examples: (1st significant figures underlined):

15 oz x 0.028 349 52 kg/oz = 0.425 24
8 kg which rounds to 0.43 kg
15 fl oz x 0.029 573 53 L/fl oz = 0.443 602 95 L which rounds to 0.44 L

(2) If the first significant digit of the metric value is SMALLER than the first significant digit of the inch-pound value, round the metric value to ONE MORE significant digit than is in the inch-pound value.

Examples: (1st significant digit underlined):

65 fl oz x 0.029 573 53 L/fl oz = 1.922 279 4 L which rounds to 1.92 L
8 ft x 0.304 8 m/ft - 2.4384 m which rounds to 2.4 m

(3) The above rules do not eliminate the necessity for using good judgment. If you believe that a dimension given as 8 ft is valid to the nearest 1/10 inch, you should consider it to mean 96.0 inches and treat it as having 3 significant digits. The rounded dimension would then be 2.438 instead of 2.4 m.

6. Placement

A. When a metric declaration of quantity of contents appears on a principal display panel (PDP) of an FDA-regulated commodity within the bottom 30 percent of the area of the PDP, the metric declaration should be placed with the required inch-pound declaration of net quantity of contents.

B. A metric declaration in the bottom 30 percent of PDP may appear as the primary declaration of quantity of contents on the PDP. This metric declaration may appear above or below or to the left or the right of the inch-pound declaration of quantity. The inch-pound declaration of quantity should not be omitted from the PDP. However, on an alternate PDP that serves solely as a foreign language PDP, FDA does not object to the foreign language PDP bearing only a metric declaration of net contents. This assumes, of course, that the container labeling otherwise complies fully with the Federal Food, Drug, and Cosmetic Act, the Fair Packaging and Labeling Act, and the regulations promulgated thereunder.

C. A metric declaration in the bottom 30 percent of PDP should comply with all provisions of FDA regulations (e.g., 21 CFR 101.105 (foods), 21 CFR 201.62 (drugs), 21 CFR 501.105 (animal food), 21 CFR 701.13 (cosmetics) and 21 CFR 801.62 (medical devices) pertaining to the required inch-pound declaration of net quantity of contents, except for provisions pertaining to a statement of count or dual statement of count or a dual statement of quantity. Manufacturers should exercise care to assure that the combined inch-pound/metric declaration complies with all location, separation, and type size requirements of the regulations and with the principles set forth in this guide. Because lower case letters are required for most metric symbols, care must be exercised to insure that both upper and lower case letters meet all letter height requirements. In lieu of the symbol, the full name of metric unit may be used, e.g., "GRAM" or "gram" or "Gram", provided the lower case letters meet the type size requirements. Exponents should be one-half the type size of the symbol letters used.

D. Use the term "Net Weight" or "Net Wt" whenever the required declaration of net quantity of contents is in terms of weight. The metric declaration may be placed before or after such terms.

E. Whenever the required declaration of net quantity of contents is in terms of fluid measure or numerical count, the terms "net" or "Net Contents" may be used in the declaration. The metric declaration may be placed before or after such terms.

F. Always use parentheses for the second expression of a dual inch-pound declaration (e.g., net weight 24 oz (1 lb 8 oz)). Additional parentheses should be used when the metric and U.S. customary declarations appear on one line.

G. Examples of inch-pound/metric declarations:

(1) Net Wt 425 g (15 oz) or Net Weight 15 oz (425 g) (assumes ounces are known to 3 significant digits, i.e., 15.0 oz)

(2) Net Wt 680 g (24 oz) (l lb 8 oz) or Net Weight 680 g (24 oz (1 lb 8 oz)) or Net Wt 24 oz (l lb 8 oz) 680 g or NET WEIGHT (680 g) 24 oz (1 lb 8 oz) (assumes ounces are known to 3 significant digits, i.e., 24.0 oz)

(3) 1 L (33.8 fl oz) (1 qt 1.8 oz) or 1 L (33.8 fl oz (1 qt 1.8 oz)) Net or Net Contents 33.8 fl oz (1 qt 1.8 oz) 1 L

Material between asterisks is new or revised

Issued: 4/1/87

Revised: 3/95

More in Compliance Policy Guides (/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/default.htm)

Foreword: Compliance Policy Guides (CPGs) (/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm116271.htm)

Chapter 1 - General (/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm116280.htm)

Chapter 2 - Biologics (/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm116336.htm)

Chapter 3 - Devices (/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm116801.htm)

Chapter 4 - Human Drugs (/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm119572.htm)

Chapter 5 - Food, Colors, and Cosmetics (/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm119194.htm)

Chapter 6 - Veterinary Medicine (/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm117042.htm)