Effective	Revised labeling due	Drug class	Mail routing code
Do	do	Antitussives	HFD–160
Do	do	Expectorants	Do.
Do	do	Inhalants	Do.
June 1, 1984	June 1, 1982	Urinary tract antiseptics	HFD–520
July 1, 1984	July 1, 1982	Chelating agents/heavy metal antagonists	HFD–110
Do	do	All other gastrointestinal drugs	HFD–110
Do	do	Antianxiety	HFD–120
Do	do	Drugs indicated for myasthenia gravis	HFD–120
Do	do	All other antiinfective drugs	HFD–520
Do	do	Bronchodilators/antiasthmatics	HFD–160
Aug. 1, 1984	Aug. 1, 1982	Estrogens	HFD–510
Do	do	Uterine stimulants	HFD–510
Do	do	Uterine relaxants	Do.
Sept. 1, 1984	Sept. 1, 1982	Drugs indicated for hypotension and shock	HFD–110
Oct. 1, 1984	Oct. 1, 1982	All other cardiac drugs	HFD–110
Do	do	Nasal decongestants	HFD–160
Nov. 1, 1984	Nov. 1, 1982	All other prescription drugs.	

[1] Except the effective date for all biological products reviewed generically by the advisory panel is 30 months after a final order is published under 21 CFR 601.25(g).
[2] Except the due date for all biological products reviewed generically by the advisory panel is 6 months after a final order is published under 21 CFR 601.25(g).

(b) Section 201.100(e) is effective April 10, 1981.

[45 FR 32552, May 16, 1980, as amended at 46 FR 7272, Jan. 23, 1981; 49 FR 14331, Apr. 11, 1984; 50 FR 8995, Mar. 6, 1985; 55 FR 11576, Mar. 29, 1990; 64 FR 400, Jan. 5, 1999]

Subpart C—Labeling Requirements for Over-the-Counter Drugs

SOURCE: 41 FR 6908, Feb. 13, 1976, unless otherwise noted.

§ 201.60 Principal display panel.

The term *principal display panel,* as it applies to over-the-counter drugs in package form and as used in this part, means the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale. The principal display panel shall be large enough to accommodate all the mandatory label information required to be placed thereon by this part with clarity and conspicuousness and without obscuring designs, vignettes, or crowding. Where packages bear alternate principal display panels, information required to be placed on the principal display panel shall be duplicated on each principal display panel. For the purpose of obtaining uniform type size in declaring the quantity of contents for all packages of substantially the same size, the term *area of the principal display panel* means the area of the side or surface that bears the principal display panel, which area shall be:

(a) In the case of a rectangular package where one entire side properly can be considered to be the principal display panel side, the product of the height times the width of that side;

(b) In the case of a cylindrical or nearly cylindrical container, 40 percent of the product of the height of the container times the circumference; and

(c) In the case of any other shape of container, 40 percent of the total surface of the container: *Provided, however,* That where such container presents an obvious ''principal display panel'' such as the top of a triangular or circular package, the area shall consist of the entire top surface.

In determining the area of the principal display panel, exclude tops, bottoms, flanges at the tops and bottoms of cans, and shoulders and necks of bottles or jars. In the case of cylindrical or nearly cylindrical containers, information required by this part to appear on the principal display panel shall appear within that 40 percent of the circumference which is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale.

§ 201.61 Statement of identity.

(a) The principal display panel of an over-the-counter drug in package form

shall bear as one of its principal features a statement of the identity of the commodity.

(b) Such statement of identity shall be in terms of the established name of the drug, if any there be, followed by an accurate statement of the general pharmacological category(ies) of the drug or the principal intended action(s) of the drug. In the case of an over-the-counter drug that is a mixture and that has no established name, this requirement shall be deemed to be satisfied by a prominent and conspicuous statement of the general pharmacological action(s) of the mixture or of its principal intended action(s) in terms that are meaningful to the layman. Such statements shall be placed in direct conjunction with the most prominent display of the proprietary name or designation and shall employ terms descriptive of general pharmacological category(ies) or principal intended action(s); for example, ''antacid,'' ''analgesic,'' ''decongestant,'' ''antihistaminic,'' etc. The indications for use shall be included in the directions for use of the drug, as required by section 502(f)(1) of the act and by the regulations in this part.

(c) The statement of identity shall be presented in bold face type on the principal display panel, shall be in a size reasonably related to the most prominent printed matter on such panel, and shall be in lines generally parallel to the base on which the package rests as it is designed to be displayed.

§ 201.62 Declaration of net quantity of contents.

(a) The label of an over-the-counter drug in package form shall bear a declaration of the net quantity of contents. This shall be expressed in the terms of weight, measure, numerical count, or a combination or numerical count and weight, measure, or size. The statement of quantity of drugs in tablet, capsule, ampule, or other unit form and the quantity of devices shall be expressed in terms of numerical count; the statement of quantity for drugs in other dosage forms shall be in terms of weight if the drug is solid, semisolid, or viscous, or in terms of fluid measure if the drug is liquid. The drug quantity statement shall be augmented when necessary to give accurate information as to the strength of such drug in the package; for example, to differentiate between several strengths of the same drug ''100 tablets, 5 grains each'' or ''100 capsules, 125 milligrams each'' or ''100 capsules, 250 milligrams each'': *Provided,* That:

(1) In the case of a firmly established, general consumer usage and trade custom of declaring the quantity of a drug in terms of linear measure or measure of area, such respective term may be used. Such term shall be augmented when necessary for accuracy of information by a statement of the weight, measure, or size of the individual units or of the entire drug; for example, the net quantity of adhesive tape in package form shall be expressed in terms of linear measure augmented by a statement of its width.

(2) Whenever the Commissioner determines for a specific packaged drug that an existing practice of declaring net quantity of contents by weight, measure, numerical count, or a combination of these does not facilitate value comparisons by consumers, he shall by regulation designate the appropriate term or terms to be used for such article.

(b) Statements of weight of the contents shall be expressed in terms of avoirdupois pound and ounce. A statement of liquid measure of the contents shall be expressed in terms of the U.S. gallon of 231 cubic inches and quart, pint, and fluid-ounce subdivisions thereof, and shall express the volume at 68 °F (20 °C). See also paragraph (p) of this section.

(c) The declaration may contain common or decimal fractions. A common fraction shall be in terms of halves, quarters, eights, sixteenths, or thirty-seconds; except that if there exists a firmly established, general consumer usage and trade custom of employing different common fractions in the net quantity declaration of a particular commodity, they may be employed. A common fraction shall be reduced to its lowest terms; a decimal fraction shall not be carried out to more than two places. A statement that includes small fractions of an ounce shall be deemed to permit smaller variations

than one which does not include such fractions.

(d) The declaration shall be located on the principal display panel of the label, and with respect to packages bearing alternate principal panels it shall be duplicated on each principal display panel.

(e) The declaration shall appear as a distinct item on the principal display panel, shall be separated, by at least a space equal to the height of the lettering used in the declaration, from other printed label information appearing above or below the declaration and, by at least a space equal to twice the width of the letter ''N'' of the style of type used in the quantity of contents statement, from other printed label information appearing to the left or right of the declaration. It shall not include any term qualifying a unit of weight, measure, or count, such as ''giant pint'' and ''full quart'', that tends to exaggerate the amount of the drug in the container. It shall be placed on the principal display panel within the bottom 30 percent of the area of the label panel in lines generally parallel to the base on which the package rests as it is designed to be displayed: *Provided,* That:

(1) On packages having a principal display panel of 5 square inches or less the requirement for placement within the bottom 30 percent of the area of the label panel shall not apply when the declaration of net quantity of contents meets the other requirements of this part; and

(2) In the case of a drug that is marketed with both outer and inner retail containers bearing the mandatory label information required by this part and the inner container is not intended to be sold separately, the net quantity of contents placement requirement of this section applicable to such inner container is waived.

(3) The principal display panel of a drug marketed on a display card to which the immediate container is affixed may be considered to be the display panel of the card, and the type size of the net quantity of contents statement is governed by the dimensions of the display card.

(f) The declaration shall accurately reveal the quantity of drug or device in the package exclusive of wrappers and other material packed therewith: *Provided,* That in the case of drugs packed in containers designed to deliver the drug under pressure, the declaration shall state the net quantity of the contents that will be expelled when the instructions for use as shown on the container are followed. The propellant is included in the net quantity declaration.

(g) The declaration shall appear in conspicuous and easily legible boldface print or type in distinct contrast (by typography, layout, color, embossing, or molding) to other matter on the package; except that a declaration of net quantity blown, embossed, or molded on a glass or plastic surface is permissible when all label information is so formed on the surface. Requirements of conspicuousness and legibility shall include the specifications that:

(1) The ratio of height to width of the letter shall not exceed a differential of 3 units to 1 unit, i.e., no more than 3 times as high as it is wide.

(2) Letter heights pertain to upper case or capital letters. When upper and lower case or all lower case letters are used, it is the lower case letter ''o'' or its equivalent that shall meet the minimum standards.

(3) When fractions are used, each component numeral shall meet one-half the minimum height standards.

(h) The declaration shall be in letters and numerals in a type size established in relationship to the area of the principal display panel of the package and shall be uniform for all packages of substantially the same size by complying with the following type specifications:

(1) Not less than one-sixteenth inch in height on packages the principal display panel of which has an area of 5 square inches or less.

(2) Not less than one-eighth inch in height on packages the principal display panel of which has an area of more than five but not more than 25 square inches.

(3) Not less than three-sixteenths inch in height on packages the principal display panel of which has an area of more than 25 but not more than 100 square inches.

(4) Not less than one-fourth inch in height on packages the principal display panel of which has an area of more than 100 square inches, except not less than one-half inch in height if the area is more than 400 square inches.

Where the declaration is blown, embossed, or molded on a glass or plastic surface rather than by printing, typing, or coloring, the lettering sizes specified in paragraphs (h) (1) through (4) of this section shall be increased by one-sixteenth of an inch.

(i) On packages containing less than 4 pounds or 1 gallon and labeled in terms of weight or fluid measure:

(1) The declaration shall be expressed both in ounces, with identification by weight or by liquid measure and, if applicable (1 pound or 1 pint or more) followed in parentheses by a declaration in pounds for weight units, with any remainder in terms of ounces or common or decimal fractions of the pound (see examples set forth in paragraphs (k) (1) and (2) of this section), or in the case of liquid measure, in the largest whole units (quarts, quarts and pints, or pints, as appropriate) with any remainder in terms of fluid ounces or common or decimal fractions of the pint or quart (see examples set forth in paragraphs (k) (3) and (4) of this section). If the net weight of the package is less than 1 ounce avoirdupois or the net fluid measure is less than 1 fluid ounce, the declaration shall be in terms of common or decimal fractions of the respective ounce and not in terms of drams.

(2) The declaration may appear in more than one line. The term *net weight* shall be used when stating the net quantity of contents in terms of weight. Use of the terms *net* or *net contents* in terms of fluid measure or numerical count is optional. It is sufficient to distinguish avoirdupois ounce from fluid ounce through association of terms; for example, ''Net wt. 6 oz'' or ''6 oz net wt.,'' and ''6 fl oz'' or ''net contents 6 fl oz''.

(j) On packages containing 4 pounds or 1 gallon or more and labeled in terms of weight or fluid measure, the declaration shall be expressed in pounds for weight units with any remainder in terms of ounces or common or decimal fractions of the pound; in the case of fluid measure, it shall be expressed in the largest whole unit (gallons, followed by common or decimal fractions of a gallon or by the next smaller whole unit or units (quarts or quarts and pints)) with any remainder in terms of fluid ounces or common or decimal fractions of the pint or quart; see paragraph (k)(5) of this section.

(k) Examples:

(1) A declaration of 1½ pounds weight shall be expressed as ''Net wt. 24 oz (1 lb 8 oz),'' or ''Net wt. 24 oz (1½ lb)'' or ''Net wt. 24 oz (1.5 lb)''.

(2) A declaration of three-fourths pound avoirdupois weight shall be expressed as ''Net wt. 12 oz''.

(3) A declaration of 1 quart liquid measure shall be expressed as ''Net contents 32 fl oz (1 qt)'' or ''32 fl oz (1 qt)''.

(4) A declaration of 1¾ quarts liquid measure shall be expressed as ''Net contents 56 fl oz (1 qt 1 pt 8 oz)'' or ''Net contents 56 fl oz (1 qt 1.5 pt),'' but not in terms of quart and ounce such as ''Net 56 fl oz (1 qt 24 oz).''

(5) A declaration of 2½ gallons liquid measure shall be expressed as ''Net contents 2 gal 2 qt,'' ''Net contents 2.5 gallons,'' or ''Net contents 2½ gal'' but not as ''2 gal 4 pt''.

(l) For quantities, the following abbreviations and none other may be employed. Periods and plural forms are optional:

Gallon gal	milliliter ml
quart qt	cubic centimeter cc
pint pt	yard yd
ounce oz	feet or foot ft
pound lb	inch in
grain gr	meter m
kilogram kg	centimeter cm
gram g	millimeter mm
milligram mg	fluid fl
microgram mcg	square sq
liter l	weight wt

(m) On packages labeled in terms of linear measure, the declaration shall be expressed both in terms of inches and, if applicable (1 foot or more), the largest whole units (yards, yards and feet, feet). The declaration in terms of the largest whole units shall be in parentheses following the declaration in terms of inches and any remainder shall be in terms of inches or common or decimal fractions of the foot or

yard; if applicable, as in the case of adhesive tape, the initial declaration in linear inches shall be preceded by a statement of the width. Examples of linear measure are ''86 inches (2 yd 1 ft 2 in),'' ''90 inches (2½ yd),'' ''30 inches (2.5 ft),'' '' ¾ inch by 36 in (1 yd),'' etc.

(n) On packages labeled in terms of area measure, the declaration shall be expressed both in terms of square inches and, if applicable (1 square foot or more), the largest whole square unit (square yards, square yards and square feet, square feet). The declaration in terms of the largest whole units shall be in parentheses following the declaration in terms of square inches and any remainder shall be in terms of square inches or common or decimal fractions of the square foot or square yard; for example, ''158 sq inches (1 sq ft 14 sq in).''

(o) Nothing in this section shall prohibit supplemental statements at locations other than the principal display panel(s) describing in nondeceptive terms the net quantity of contents, provided that such supplemental statements of net quantity of contents shall not include any term qualifying a unit of weight, measure, or count that tends to exaggerate the amount of the drug contained in the package; for example, ''giant pint'' and ''full quart.'' Dual or combination declarations of net quantity of contents as provided for in paragraphs (a) and (i) of this section are not regarded as supplemental net quantity statements and shall be located on the principal display panel.

(p) A separate statement of net quantity of contents in terms of the metric system of weight or measure is not regarded as a supplemental statement and an accurate statement of the net quantity of contents in terms of the metric system of weight or measure may also appear on the principal display panel or on other panels.

(q) The declaration of net quantity of contents shall express an accurate statement of the quantity of contents of the package. Reasonable variations caused by loss or gain of moisture during the course of good distribution practice or by unavoidable deviations in good manufacturing practice will be recognized. Variations from stated quantity of contents shall not be unreasonably large.

(r) A drug shall be exempt from compliance with the net quantity declaration required by this section if it is an ointment labeled ''sample,'' ''physician's sample,'' or a substantially similar statement and the contents of the package do not exceed 8 grams.

§ 201.63 Pregnancy/breast-feeding warning.

(a) The labeling for all over-the-counter (OTC) drug products that are intended for systemic absorption, unless specifically exempted, shall contain a general warning under the heading ''Warning'' (or ''Warnings'' if it appears with additional warning statements) as follows: ''If pregnant or breast-feeding, ask a health professional before use.'' [first four words of this statement in bold type] In addition to the written warning, a symbol that conveys the intent of the warning may be used in labeling.

(b) Where a specific warning relating to use during pregnancy or while nursing has been established for a particular drug product in a new drug application (NDA) or for a product covered by an OTC drug final monograph in part 330 of this chapter, the specific warning shall be used in place of the warning in paragraph (a) of this section, unless otherwise stated in the NDA or in the final OTC drug monograph.

(c) The following OTC drugs are exempt from the provisions of paragraph (a) of this section:

(1) Drugs that are intended to benefit the fetus or nursing infant during the period of pregnancy or nursing.

(2) Drugs that are labeled exclusively for pediatric use.

(d) The Food and Drug Administration will grant an exemption from paragraph (a) of this section where appropriate upon petition under the provisions of § 10.30 of this chapter. Decisions with respect to requests for exemptions shall be maintained in a permanent file for public review by the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

(e) The labeling of orally or rectally administered OTC aspirin and aspirin-containing drug products must bear a warning that immediately follows the general warning identified in paragraph (a) of this section. The warning shall be as follows:

''It is especially important not to use'' (select ''aspirin'' or ''carbaspirin calcium,'' as appropriate) ''during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.''

[47 FR 54757, Dec. 3, 1982, as amended at 55 FR 27784, July 5, 1990; 59 FR 14364, Mar. 28, 1994; 64 FR 13286, Mar. 17, 1999; 68 FR 24879, May 9, 2003]

§ 201.64 Sodium labeling.

(a) The labeling of over-the-counter (OTC) drug products intended for oral ingestion shall contain the sodium content per dosage unit (e.g., tablet, teaspoonful) if the sodium content of a single maximum recommended dose of the product (which may be one or more dosage units) is 5 milligrams or more. OTC drug products intended for oral ingestion include gum and lozenge dosage forms, but do not include dentifrices, mouthwashes, or mouth rinses.

(b) The sodium content shall be expressed in milligrams per dosage unit and shall include the total amount of sodium regardless of the source, i.e., from both active and inactive ingredients. The sodium content shall be rounded-off to the nearest whole number. The sodium content per dosage unit shall follow the heading ''Other information'' as stated in § 201.66(c)(7).

(c) The labeling of OTC drug products intended for oral ingestion shall contain the following statement under the heading ''Warning'' (or ''Warnings'' if it appears with additional warning statements) if the amount of sodium present in the labeled maximum daily dose of the product is more than 140 milligrams: ''Ask a doctor before use if you have [in bold type] [bullet][1] a sodium-restricted diet''. The warnings in §§ 201.64(c), 201.70(c), 201.71(c), and 201.72(c) may be combined, if applicable, provided the ingredients are listed in alphabetical order, e g., a calcium or sodium restricted diet.

(d) The term *sodium free* may be used in the labeling of OTC drug products intended for oral ingestion if the amount of sodium in the labeled maximum daily dose is 5 milligrams or less and the amount of sodium per dosage unit is 0 milligram (when rounded-off in accord with paragraph (b) of this section).

(e) The term *very low sodium* may be used in the labeling of OTC drug products intended for oral ingestion if the amount of sodium in the labeled maximum daily dose is 35 milligrams or less.

(f) The term *low sodium* may be used in the labeling of OTC drug products intended for oral ingestion if the amount of sodium in the labeled maximum daily dose is 140 milligrams or less.

(g) The term *salt* is not synonymous with the term sodium and shall not be used interchangeably or substituted for the term *sodium.*

(h) The terms *sodium free, very low sodium,* and *low sodium* shall be in print size and style no larger than the product's statement of identity and shall not be unduly prominent in print size or style compared to the statement of identity.

(i) Any product subject to this paragraph that contains sodium bicarbonate, sodium phosphate, or sodium biphosphate as an active ingredient for oral ingestion and that is not labeled as required by this paragraph and that is initially introduced or initially delivered for introduction into interstate commerce after April 22, 1997, is misbranded under sections 201(n) and 502 (a) and (f) of the Federal Food, Drug, and Cosmetic Act (the act).

(j) Any product subject to paragraphs (a) through (h) of this section that is not labeled as required and that is initially introduced or initially delivered for introduction into interstate commerce after the following dates is misbranded under sections 201(n) and 502(a) and (f) of the Federal Food, Drug, and Cosmetic Act.

(1) As of the date of approval of the application for any single entity and combination products subject to drug

[1] See § 201 .66(b)(4) of this chapter for definition of bullet symbol.

marketing applications approved on or after April 23, 2004.

(2) Septemeber 24, 2005, for all OTC drug products subject to any OTC drug monograph, not yet the subject of any OTC drug monograph, or subject to drug marketing applications approved before April 23, 2004.

[61 FR 17806, Apr. 22, 1996, as amended at 62 FR 19925, Apr. 24, 1997; 64 FR 13286, Mar. 17, 1999; 69 FR 13724, Mar. 24, 2004]

EFFECTIVE DATE NOTE: At 69 FR 69280, Nov. 29, 2004, § 201.64 was amended by adding paragraph (k), effective Nov. 29, 2005. For the convenience of the user, the added text is set forth as follows:

§ 201.64 Sodium labeling.

* * * * *

(k) The labeling of OTC drug products intended for rectal administration containing dibasic sodium phosphate and/or monobasic sodium phosphate shall contain the sodium content per delivered dose if the sodium content is 5 milligrams or more. The sodium content shall be expressed in milligrams or grams. If less than 1 gram, milligrams should be used. The sodium content shall be rounded-off to the nearest whole number if expressed in milligrams (or nearest tenth of a gram if expressed in grams). The sodium content per delivered dose shall follow the heading ''Other information'' as stated in § 201.66(c)(7). Any product subject to this paragraph that contains dibasic sodium phosphate and/or monobasic sodium phosphate as an active ingredient intended for rectal administration and that is not labeled as required by this paragraph and that is initially introduced or initially delivered for introduction into interstate commerce after November 29, 2005, is misbranded under sections 201(n) and 502(a) and (f) of the act.

§ 201.66 Format and content requirements for over-the-counter (OTC) drug product labeling.

(a) *Scope.* This section sets forth the content and format requirements for the labeling of all OTC drug products. Where an OTC drug product is the subject of an applicable monograph or regulation that contains content and format requirements that conflict with this section, the content and format requirements in this section must be followed unless otherwise specifically provided in the applicable monograph or regulation.

(b) *Definitions.* The following definitions apply to this section:

(1) *Act* means the Federal Food, Drug, and Cosmetic Act (secs. 201 *et seq.* (21 U.S.C. 321 *et seq.*)).

(2) *Active ingredient* means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of humans. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect.

(3) *Approved drug application* means a new drug (NDA) or abbreviated new drug (ANDA) application approved under section 505 of the act (21 U.S.C. 355).

(4) *Bullet* means a geometric symbol that precedes each statement in a list of statements. For purposes of this section, the bullet style is limited to solid squares or solid circles, in the format set forth in paragraph (d)(4) of this section.

(5) *Established name* of a drug or ingredient thereof means the applicable official name designated under section 508 of the act (21 U.S.C. 358), or, if there is no designated official name and the drug or ingredient is recognized in an official compendium, the official title of the drug or ingredient in such compendium, or, if there is no designated official name and the drug or ingredient is not recognized in an official compendium, the common or usual name of the drug or ingredient.

(6) *FDA* means the Food and Drug Administration.

(7) *Heading* means the required statements in quotation marks listed in paragraphs (c)(2) through (c)(9) of this section, excluding subheadings (as defined in paragraph (a)(9) of this section).

(8) *Inactive ingredient* means any component other than an active ingredient.

(9) *Subheading* means the required statements in quotation marks listed in paragraphs (c)(5)(ii) through (c)(5)(vii) of this section.

(10) *Drug facts labeling* means the title, headings, subheadings, and information required under or otherwise described in paragraph (c) of this section.

(11) *Title* means the heading listed at the top of the required OTC drug product labeling, as set forth in paragraph (c)(1) of this section.

(12) *Total surface area available to bear labeling* means all surfaces of the outside container of the retail package or, if there is no such outside container, all surfaces of the immediate container or container wrapper except for the flanges at the tops and bottoms of cans and the shoulders and necks of bottles and jars.

(c) *Content requirements.* The outside container or wrapper of the retail package, or the immediate container label if there is no outside container or wrapper, shall contain the title, headings, subheadings, and information set forth in paragraphs (c)(1) through (c)(8) of this section, and may contain the information under the heading in paragraph (c)(9) of this section, in the order listed.

(1) (Title) ''Drug Facts''. If the drug facts labeling appears on more than one panel, the title ''Drug Facts (continued)'' shall appear at the top of each subsequent panel containing such information.

(2) ''Active ingredient'' or ''Active ingredients'' ''(in each [insert the dosage unit stated in the directions for use (e.g., tablet, 5 mL teaspoonful) or in each gram as stated in §§ 333.110 and 333.120 of this chapter])'', followed by the established name of each active ingredient and the quantity of each active ingredient per dosage unit. Unless otherwise provided in an applicable OTC drug monograph or approved drug application, products marketed without discrete dosage units (e.g., topicals) shall state the proportion (rather than the quantity) of each active ingredient.

(3) ''Purpose'' or ''Purposes'', followed by the general pharmacological category(ies) or the principal intended action(s) of the drug or, where the drug consists of more than one ingredient, the general pharmacological categories or the principal intended actions of each active ingredient. When an OTC drug monograph contains a statement of identity, the pharmacological action described in the statement of identity shall also be stated as the purpose of the active ingredient.

(4) ''Use'' or ''Uses'', followed by the indication(s) for the specific drug product.

(5) ''Warning'' or ''Warnings'', followed by one or more of the following, if applicable:

(i) ''For external use only'' [in bold type] for topical drug products not intended for ingestion, or ''For'' (select one of the following, as appropriate: ''rectal'' or ''vaginal'') ''use only'' [in bold type].

(ii) All applicable warnings listed in paragraphs (c)(5)(ii)(A) through (c)(5)(ii)(G) of this section with the appropriate subheadings highlighted in bold type:

(A) Reye's syndrome warning for drug products containing salicylates set forth in § 201.314(h)(1). This warning shall follow the subheading ''Reye's syndrome:''

(B) Allergic reaction warnings set forth in any applicable OTC drug monograph or approved drug application for any product that requires a separate allergy warning. This warning shall follow the subheading ''Allergy alert:''

(C) Flammability warning, with appropriate flammability signal word(s) (e.g., §§ 341.74(c)(5)(iii), 344.52(c), 358.150(c), and 358.550(c) of this chapter). This warning shall follow a subheading containing the appropriate flammability signal word(s) described in an applicable OTC drug monograph or approved drug application.

(D) Water soluble gums warning set forth in § 201.319. This warning shall follow the subheading ''Choking:''

(E) Alcohol warning set forth in § 201.322. This warning shall follow the subheading ''Alcohol warning:''

(F) Sore throat warning set forth in § 201.315. This warning shall follow the subheading ''Sore throat warning:''

(G) Warning for drug products containing sodium phosphates set forth in § 201.307(b)(2)(i) or (b)(2)(ii). This warning shall follow the subheading ''Dosage warning:''

(iii) ''Do not use'' [in bold type], followed by all contraindications for use with the product. These contraindications are absolute and are intended for situations in which consumers should not use the product unless a prior diagnosis has been established by a doctor

or for situations in which certain consumers should not use the product under any circumstances regardless of whether a doctor or health professional is consulted.

(iv) ''Ask a doctor before use if you have'' [in bold type] or, for products labeled only for use in children under 12 years of age, ''Ask a doctor before use if the child has'' [in bold type], followed by all warnings for persons with certain preexisting conditions (excluding pregnancy) and all warnings for persons experiencing certain symptoms. The warnings under this heading are those intended only for situations in which consumers should not use the product until a doctor is consulted.

(v) ''Ask a doctor or pharmacist before use if you are'' [in bold type] or, for products labeled only for use in children under 12 years of age, ''Ask a doctor or pharmacist before use if the child is'' [in bold type], followed by all drug-drug and drug-food interaction warnings.

(vi) ''When using this product'' [in bold type], followed by the side effects that the consumer may experience, and the substances (e.g., alcohol) or activities (e.g., operating machinery, driving a car, warnings set forth in §369.21 of this chapter for drugs in dispensers pressurized by gaseous propellants) to avoid while using the product.

(vii) ''Stop use and ask a doctor if'' [in bold type], followed by any signs of toxicity or other reactions that would necessitate immediately discontinuing use of the product.

(viii) Any required warnings in an applicable OTC drug monograph, other OTC drug regulations, or approved drug application that do not fit within one of the categories listed in paragraphs (c)(5)(i) through (c)(5)(vii), (c)(5)(ix), and (c)(5)(x) of this section.

(ix) The pregnancy/breast-feeding warning set forth in §201.63(a); the third trimester warning set forth in §201.63(e) for products containing aspirin or carbaspirin calcium; the third trimester warning set forth in approved drug applications for products containing ketoprofen, naproxen sodium, and ibuprofen (not intended exclusively for use in children).

(x) The ''Keep out of reach of children'' warning and the accidental overdose/ingestion warning set forth in §330.1(g) of this chapter.

(6) ''Directions'', followed by the directions for use described in an applicable OTC drug monograph or approved drug application.

(7) ''Other information'', followed by additional information that is not included under paragraphs (c)(2) through (c)(6), (c)(8), and (c)(9) of this section, but which is required by or is made optional under an applicable OTC drug monograph, other OTC drug regulation, or is included in the labeling of an approved drug application.

(i) Required information about certain ingredients in OTC drug products (e.g., sodium in §201.64(b), calcium in §201.70(b), magnesium in §201.71(b), and potassium in §201.72(b)) shall appear as follows: ''each (insert appropriate dosage unit) contains:'' [in bold type (insert name(s) of ingredient(s) (in alphabetical order) and the quantity of each ingredient). This information shall be the first statement under this heading.

(ii) The phenylalanine/aspartame content required by §201.21(b), if applicable, shall appear as the next item of information.

(iii) Additional information that is authorized to appear under this heading shall appear as the next item(s) of information. There is no required order for this subsequent information.

(8) ''Inactive ingredients'', followed by a listing of the established name of each inactive ingredient. If the product is an OTC drug product that is not also a cosmetic product, then the inactive ingredients shall be listed in alphabetical order. If the product is an OTC drug product that is also a cosmetic product, then the inactive ingredients shall be listed as set forth in §701.3(a) or (f) of this chapter, the names of cosmetic ingredients shall be determined in accordance with §701.3(c) of this chapter, and the provisions in §701.3(e), (g), (h), (l), (m), (n), and (o) of this chapter and §720.8 of this chapter may also apply, as appropriate. If there is a difference in the labeling provisions in this §201.66 and §§701.3 and 720.8 of this chapter, the labeling provisions in this §201.66 shall be used.

(9) ''Questions?'' or ''Questions or comments?'', followed by the telephone number of a source to answer questions

about the product. It is recommended that the days of the week and times of the day when a person is available to respond to questions also be included. A graphic of a telephone or telephone receiver may appear before the heading. The telephone number must appear in a minimum 6-point bold type.

(d) *Format requirements.* The title, headings, subheadings, and information set forth in paragraphs (c)(1) through (c)(9) of this section shall be presented on OTC drug products in accordance with the following specifications. In the interest of uniformity of presentation, FDA strongly reccommends that the Drug Facts labeling be presented using the graphic specifications set forth in appendix A to part 201.

(1) The title ''Drug Facts'' or ''Drug Facts (continued)'' shall use uppercase letters for the first letter of the words ''Drug'' and ''Facts.'' All headings and subheadings in paragraphs (c)(2) through (c)(9) of this section shall use an uppercase letter for the first letter in the first word and lowercase letters for all other words. The title, headings, and subheadings in paragraphs (c)(1), (c)(2), and (c)(4) through (c)(9) of this section shall be left justified.

(2) The letter height or type size for the title ''Drug Facts'' shall appear in a type size larger than the largest type size used in the Drug Facts labeling. The letter height or type size for the title ''Drug Facts (continued)'' shall be no smaller than 8-point type. The letter height or type size for the headings in paragraphs (c)(2) through (c)(9) of this section shall be the larger of either 8-point or greater type, or 2-point sizes greater than the point size of the text. The letter height or type size for the subheadings and all other information described in paragraphs (c)(2) through (c)(9) of this section shall be no smaller than 6-point type.

(3) The title, heading, subheadings, and information in paragraphs (c)(1) through (c)(9) of this section shall be legible and clearly presented, shall have at least 0.5-point leading (i.e., space between two lines of text), and shall not have letters that touch. The type style for the title, headings, subheadings, and all other required information described in paragraphs (c)(2) through (c)(9) of this section shall be any single, clear, easy-to-read type style, with no more than 39 characters per inch. The title and headings shall be in bold italic, and the subheadings shall be in bold type, except that the word ''(continued)'' in the title ''Drug Facts (continued)'' shall be regular type. The type shall be all black or one color printed on a white or other contrasting background, except that the title and the headings may be presented in a single, alternative, contrasting color unless otherwise provided in an approved drug application, OTC drug monograph (e.g., current requirements for bold print in §§ 341.76 and 341.80 of this chapter), or other OTC drug regulation (e.g., the requirement for a box and red letters in § 201.308(c)(1)).

(4) When there is more than one statement, each individual statement listed under the headings and subheadings in paragraphs (c)(4) through (c)(7) of this section shall be preceded by a solid square or solid circle bullet of 5-point type size. Bullets shall be presented in the same shape and color throughout the labeling. The first bulleted statement on each horizontal line of text shall be either left justified or separated from an appropriate heading or subheading by at least two square ''ems'' (i.e., two squares of the size of the letter ''M''). If more than one bulleted statement is placed on the same horizontal line, the end of one bulleted statement shall be separated from the beginning of the next bulleted statement by at least two square ''ems'' and the complete additional bulleted statement(s) shall not continue to the next line of text. Additional bulleted statements appearing on each subsequent horizontal line of text under a heading or subheading shall be vertically aligned with the bulleted statements appearing on the previous line.

(5) The title, headings, subheadings, and information set forth in paragraphs (c)(1) through (c)(9) of this section may appear on more than one panel on the outside container of the retail package, or the immediate container label if there is no outside container or wrapper. The continuation of the required content and format onto

multiple panels must retain the required order and flow of headings, subheadings, and information. A visual graphic (e.g., an arrow) shall be used to signal the continuation of the Drug Facts labeling to the next adjacent panel.

(6) The heading and information required under paragraph (c)(2) of this section shall appear immediately adjacent and to the left of the heading and information required under paragraph (c)(3) of this section. The active ingredients and purposes shall be aligned under the appropriate headings such that the heading and information required under paragraph (c)(2) of this section shall be left justified and the heading and information required under paragraph (c)(3) of this section shall be right justified. If the OTC drug product contains more than one active ingredient, the active ingredients shall be listed in alphabetical order. If more than one active ingredient has the same purpose, the purpose need not be repeated for each active ingredient, provided the information is presented in a manner that readily associates each active ingredient with its purpose (i.e., through the use of brackets, dot leaders, or other graphical features). The information described in paragraphs (c)(4) and (c)(6) through (c)(9) of this section may start on the same line as the required headings. None of the information described in paragraph (c)(5) of this section shall appear on the same line as the ''Warning'' or ''Warnings'' heading.

(7) Graphical images (e.g., the UPC symbol) and information not described in paragraphs (c)(1) through (c)(9) of this section shall not appear in or in any way interrupt the required title, headings, subheadings, and information in paragraphs (c)(1) through (c)(9) of this section. Hyphens shall not be used except to punctuate compound words.

(8) The information described in paragraphs (c)(1) through (c)(9) of this section shall be set off in a box or similar enclosure by the use of a barline. A distinctive horizontal barline extending to each end of the ''Drug Facts'' box or similar enclosure shall provide separation between each of the headings listed in paragraphs (c)(2) through (c)(9) of this section. When a heading listed in paragraphs (c)(2) through (c)(9) of this section appears on a subsequent panel immediately after the ''Drug Facts (continued)'' title, a horizontal hairline shall follow the title and immediately precede the heading. A horizontal hairline extending within two spaces on either side of the ''Drug Facts'' box or similar enclosure shall immediately follow the title and shall immediately precede each of the subheadings set forth in paragraph (c)(5) of this section, except the subheadings in paragraphs (c)(5)(ii)(A) through (c)(5)(ii)(G) of this section.

(9) The information set forth in paragraph (c)(6) of this section under the heading ''Directions'' shall appear in a table format when dosage directions are provided for three or more age groups or populations. The last line of the table may be the horizontal barline immediately preceding the heading of the next section of the labeling.

(10) If the title, headings, subheadings, and information in paragraphs (c)(1) through (c)(9) of this section, printed in accordance with the specifications in paragraphs (d)(1) through (d)(9) of this section, and any other FDA required information for drug products, and, as appropriate, cosmetic products, other than information required to appear on a principle display panel, requires more than 60 percent of the total surface area available to bear labeling, then the Drug Facts labeling shall be printed in accordance with the specifications set forth in paragraphs (d)(10)(i) through (d)(10)(v) of this section. In determining whether more than 60 percent of the total surface area available to bear labeling is required, the indications for use listed under the ''Use(s)'' heading, as set forth in paragraph (c)(4) of this section, shall be limited to the minimum required uses reflected in the applicable monograph, as provided in § 330.1(c)(2) of this chapter.

(i) Paragraphs (d)(1), (d)(5), (d)(6), and (d)(7) of this section shall apply.

(ii) Paragraph (d)(2) of this section shall apply except that the letter height or type size for the title ''Drug Facts (continued)'' shall be no smaller than 7-point type and the headings in paragraphs (c)(2) through (c)(9) of this section shall be the larger of either 7-

point or greater type, or 1-point size greater than the point size of the text.

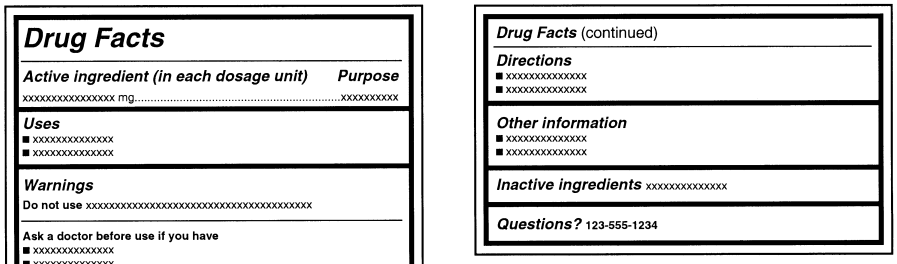
(iii) Paragraph (d)(3) of this section shall apply except that less than 0.5-point leading may be used, provided the ascenders and descenders do not touch.

(iv) Paragraph (d)(4) of this section shall apply except that if more than one bulleted statement is placed on the same horizontal line, the additional bulleted statements may continue to the next line of text, and except that the bullets under each heading or subheading need not be vertically aligned.

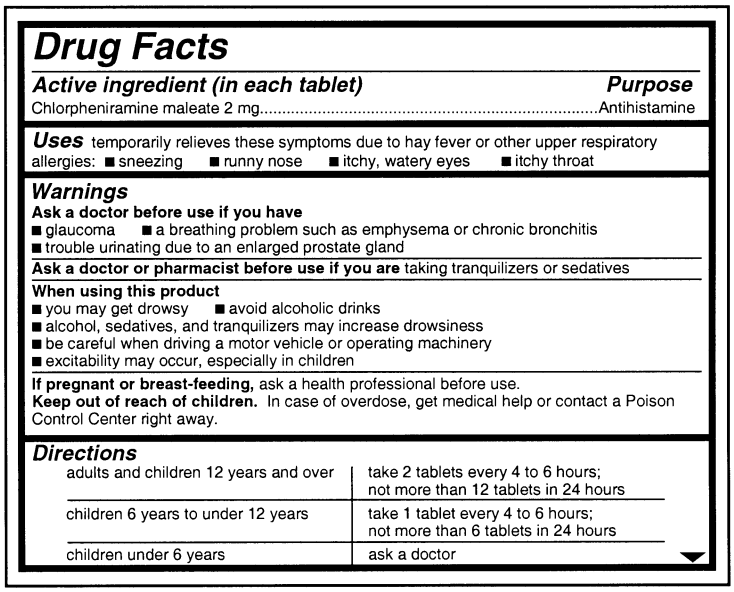
(v) Paragraph (d)(8) of this section shall apply except that the box or similar enclosure required in paragraph (d)(8) of this section may be omitted if the Drug Facts labeling is set off from the rest of the labeling by use of color contrast.

(11)(i) The following labeling outlines the various provisions in paragraphs (c) and (d) of this section:

OTC Drug Product Labeling Outline



(ii) The following sample label illustrates the provisions in paragraphs (c) and (d) of this section:



Drug Facts

Active ingredient (in each tablet) ***Purpose***

Chlorpheniramine maleate 2 mg.....Antihistamine

Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ sneezing ■ runny nose ■ itchy, watery eyes ■ itchy throat

Warnings

Ask a doctor before use if you have

■ glaucoma ■ a breathing problem such as emphysema or chronic bronchitis
■ trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives

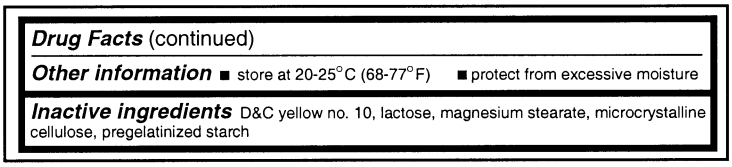
When using this product

■ you may get drowsy ■ avoid alcoholic drinks
■ alcohol, sedatives, and tranquilizers may increase drowsiness
■ be careful when driving a motor vehicle or operating machinery
■ excitability may occur, especially in children

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

adults and children 12 years and over	take 2 tablets every 4 to 6 hours; not more than 12 tablets in 24 hours
children 6 years to under 12 years	take 1 tablet every 4 to 6 hours; not more than 6 tablets in 24 hours
children under 6 years	ask a doctor

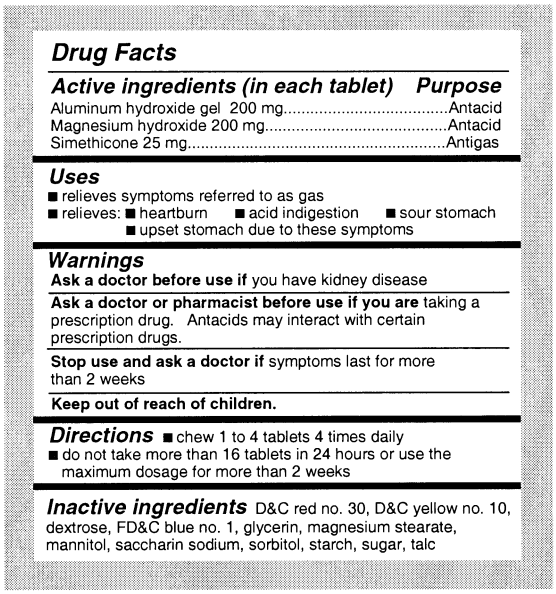


Drug Facts (continued)

Other information ■ store at 20-25°C (68-77°F) ■ protect from excessive moisture

Inactive ingredients D&C yellow no. 10, lactose, magnesium stearate, microcrystalline cellulose, pregelatinized starch

(iii) The following sample label illustrates the provisions in paragraphs (c) and (d) of this section, including paragraph (d)(10) of this section, which permits modifications for small packages:



Drug Facts

Active ingredients (in each tablet)	Purpose
Aluminum hydroxide gel 200 mg	Antacid
Magnesium hydroxide 200 mg	Antacid
Simethicone 25 mg	Antigas

Uses

- relieves symptoms referred to as gas
- relieves: ■ heartburn ■ acid indigestion ■ sour stomach ■ upset stomach due to these symptoms

Warnings

Ask a doctor before use if you have kidney disease

Ask a doctor or pharmacist before use if you are taking a prescription drug. Antacids may interact with certain prescription drugs.

Stop use and ask a doctor if symptoms last for more than 2 weeks

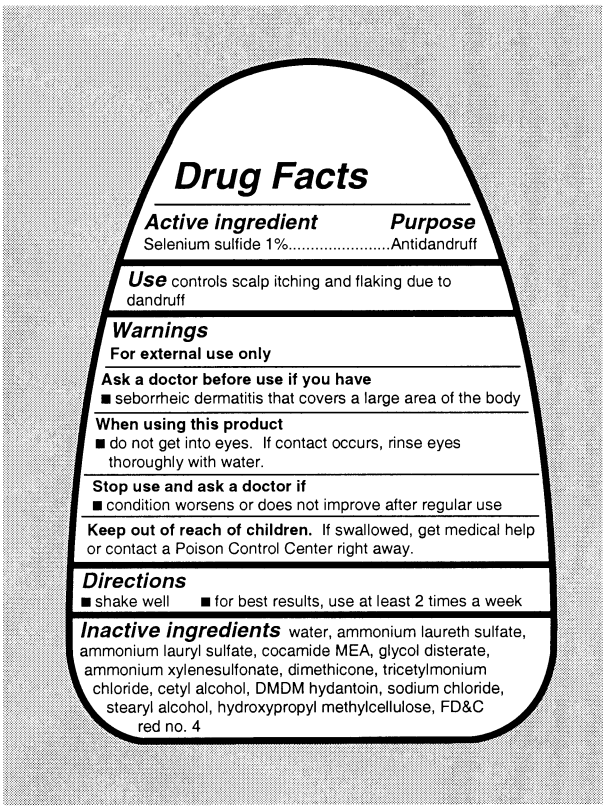
Keep out of reach of children.

Directions

- chew 1 to 4 tablets 4 times daily
- do not take more than 16 tablets in 24 hours or use the maximum dosage for more than 2 weeks

Inactive ingredients D&C red no. 30, D&C yellow no. 10, dextrose, FD&C blue no. 1, glycerin, magnesium stearate, mannitol, saccharin sodium, sorbitol, starch, sugar, talc

(iv) The following sample label illustrates the provisions in paragraphs (c) and (d) of this section for a drug product marketed with cosmetic claims:



(e) *Exemptions and deferrals.* FDA on its own initiative or in response to a written request from any manufacturer, packer, or distributor, may exempt or defer, based on the circumstances presented, one or more specific requirements set forth in this section on the basis that the requirement is inapplicable, impracticable, or contrary to public health or safety. Requests for exemptions shall be submitted in three copies in the form of an ''Application for Exemption'' to the Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. The request shall be clearly identified on the envelope as a ''Request for Exemption from 21 CFR 201.66 (OTC Labeling Format)'' and shall be directed to Docket No. 98N–0337. A separate request shall be submitted for each OTC drug product. Sponsors of a product marketed under an approved drug application shall also submit a single copy of the exemption request to their application. Decisions on exemptions and deferrals will be maintained in a permanent file in this docket for public review. Exemption and deferral requests shall:

(1) Document why a particular requirement is inapplicable, impracticable, or is contrary to public health or safety; and

(2) Include a representation of the proposed labeling, including any outserts, panel extensions, or other graphical or packaging techniques intended to be used with the product.

(f) *Interchangeable terms and connecting terms.* The terms listed in § 330.1(i) of this chapter may be used

interchangeably in the labeling of OTC drug products, provided such use does not alter the meaning of the labeling that has been established and identified in an applicable OTC drug monograph or by regulation. The terms listed in §330.1(j) of this chapter may be deleted from the labeling of OTC drug products when the labeling is revised to comply with this section, provided such deletion does not alter the meaning of the labeling that has been established and identified in an applicable OTC drug monograph or by regulation. The terms listed in §330.1(i) and (j) of this chapter shall not be used to change in any way the specific title, headings, and subheadings required under paragraphs (c)(1) through (c)(9) of this section.

(g) *Regulatory action.* An OTC drug product that is not in compliance with the format and content requirements in this section is subject to regulatory action.

[64 FR 13286, Mar. 17, 1999, as amended at 65 FR 8, Jan. 3, 2000; 65 FR 48904, Aug. 10, 2000; 69 FR 13733, Mar. 24, 2004]

§201.70 Calcium labeling.

(a) The labeling of over-the-counter (OTC) drug products intended for oral ingestion shall contain the calcium content per dosage unit (e.g., tablet, teaspoonful) if the calcium content of a single maximum recommended dose of the product (which may be one or more dosage units) is 20 milligrams or more. OTC drug products intended for oral ingestion include gum and lozenge dosage forms, but do not include dentifrices, mouthwashes, or mouth rinses.

(b) The calcium content shall be expressed in milligrams or grams per dosage unit and shall include the total amount of calcium regardless of the source, i.e., from both active and inactive ingredients. If the dosage unit contains less than 1 gram of calcium, milligrams should be used. The calcium content per dosage unit shall be rounded-off to the nearest 5 milligrams (or nearest tenth of a gram if over 1 gram). The calcium content per dosage unit shall follow the heading ''Other information'' as stated in §201.66(c)(7).

(c) The labeling of OTC drug products intended for oral ingestion shall contain the following statement under the heading ''Warning'' (or ''Warnings'' if it appears with additional warning statements) if the amount of calcium present in the labeled maximum daily dose of the product is more than 3.2 grams: ''Ask a doctor before use if you have [in bold type] [bullet][1] kidney stones [bullet] a calcium-restricted diet''. The warnings in §§201.64(c), 201.70(c), 201.71(c), and 201.72(c) may be combined, if applicable, provided the ingredients are listed in alphabetical order, e.g., a calcium or sodium restricted diet.

(d) Any product subject to this paragraph that is not labeled as required by this paragraph and that is initially introduced or initially delivered for introduction into interstate commerce after the following dates is misbranded under sections 201(n) and 502(a) and (f) of the Federal Food, Drug, and Cosmetic Act.

(1) As of the date of approval of the application for any single entity and combination products subject to drug marketing applications approved on or after April 23, 2004.

(2) September 24, 2005, for all OTC drug products subject to any OTC drug monograph, not yet the subject of any OTC drug monograph, or subject to drug marketing applications approved before April 23, 2004.

[69 FR 13733, Mar. 24, 2004]

§201.71 Magnesium labeling.

(a) The labeling of over-the-counter (OTC) drug products intended for oral ingestion shall contain the magnesium content per dosage unit (e.g., tablet, teaspoonful) if the magnesium content of a single maximum recommended dose of the product (which may be one or more dosage units) is 8 milligrams or more. OTC drug products intended for oral ingestion include gum and lozenge dosage forms, but do not include dentifrices, mouthwashes, or mouth rinses.

(b) The magnesium content shall be expressed in milligrams or grams per dosage unit and shall include the total amount of magnesium regardless of the

[1] See §201.66(b)(4) of this chapter for definition of bullet symbol.

source, i.e., from both active and inactive ingredients. If the dosage unit contains less than 1 gram of magnesium, milligrams should be used. The magnesium content shall be rounded-off to the nearest 5 milligrams (or nearest tenth of a gram if over 1 gram). The magnesium content per dosage unit shall follow the heading ''Other information'' as stated in § 201.66(c)(7).

(c) The labeling of OTC drug products intended for oral ingestion shall contain the following statement under the heading ''Warning'' (or ''Warnings'' if it appears with additional warning statements) if the amount of magnesium present in the labeled maximum daily dose of the product is more than 600 milligrams: ''Ask a doctor before use if you have [in bold type] [bullet][1] kidney disease [bullet] a magnesium-restricted diet''. The warnings in §§ 201.64(c), 201.70(c), 201.71(c), and 201.72(c) may be combined, if applicable, provided the ingredients are listed in alphabetical order, e.g., a magnesium or potassium-restricted diet.

(d) Any product subject to this paragraph that is not labeled as required by this paragraph and that is initially introduced or initially delivered for introduction into interstate commerce after the following dates is misbranded under sections 201(n) and 502(a) and (f) of the Federal Food, Drug, and Cosmetic Act.

(1) As of the date of approval of the application for any single entity and combination products subject to drug marketing applications approved on or after April 23, 2004.

(2) September 24. 2005, for all OTC drug products subject to any OTC drug monograph, not yet the subject of any OTC drug monograph, or subject to drug marketing applications approved before April 23, 2004.

[69 FR 13734, Mar. 24, 2004]

§ 201.72 Potassium labeling.

(a) The labeling of over-the-counter (OTC) drug products intended for oral ingestion shall contain the potassium content per dosage unit (e.g., tablet, teaspoonful) if the potassium content of a single maximum recommended dose of the product (which may be one or more dosage units) is 5 milligrams or more. OTC drug products intended for oral ingestion include gum and lozenge dosage forms, but do not include dentifrices, mouthwashes, or mouth rinses.

(b) The potassium content shall be expressed in milligrams or grams per dosage unit and shall include the total amount of potassium regardless of the source, i.e., from both active and inactive ingredients. If the dosage unit contains less than 1 gram of potassium, milligrams should be used. The potassium content shall be rounded-off to the nearest 5 milligrams (or nearest tenth of a gram if over 1 gram). The potassium content per dosage unit shall follow the heading ''Other information'' as stated in § 201.66(c)(7).

(c) The labeling of OTC drug products intended for oral ingestion shall contain the following statement under the heading ''Warning'' (or ''Warnings'' if it appears with additional warning statements) if the amount of potassium present in the labeled maximum daily dose of the product is more than 975 milligrams: ''Ask a doctor before use if you have [in bold type] [bullet][1] kidney disease [bullet] a potassium-restricted diet''. The warnings in §§ 201.64(c), 201.70(c), 201.71(c), and 201.72(c) may be combined, if applicable, provided the ingredients are listed in alphabetical order, e.g., a magnesium or potassium-restricted diet.

(d) Any product subject to this paragraph that is not labeled as required by this paragraph and that is initially introduced or initially delivered for introduction into interstate commerce after the following dates is misbranded under sections 201(n) and 502(a) and (f) of the Federal Food, Drug, and Cosmetic Act.

(1) As of the date of approval of the application for any single entity and combination products subject to drug marketing applications approved on or after April 23, 2004.

(2) September 24, 2005, for all OTC drug products subject to any OTC drug monograph, not yet the subject of any OTC drug monograph, or subject to

[1] See § 201.66(b)(4) of this chapter for definition of bullet symbol.

[1] See § 201.66(b)(4) of this chapter for definition of bullet symbol.

drug marketing applications approved before April 23, 2004.

[69 FR 13734, Mar. 24, 2004]

Subpart D—Exemptions From Adequate Directions for Use

§ 201.100 Prescription drugs for human use.

A drug subject to the requirements of section 503(b)(1) of the act shall be exempt from section 502(f)(1) if all the following conditions are met:

(a) The drug is:

(1)(i) In the possession of a person (or his agents or employees) regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale distribution of prescription drugs; or

(ii) In the possession of a retail, hospital, or clinic pharmacy, or a public health agency, regularly and lawfully engaged in dispensing prescription drugs; or

(iii) In the possession of a practitioner licensed by law to administer or prescribe such drugs; and

(2) It is to be dispensed in accordance with section 503(b)

(b) The label of the drug bears:

(1) The statement ''Rx only'' and

(2) The recommended or usual dosage and

(3) The route of administration, if it is not for oral use; and

(4) The quantity or proportion of each active ingredient, as well as the information required by section 502 (d) and (e); and

(5) If it is for other than oral use, the names of all inactive ingredients, except that:

(i) Flavorings and perfumes may be designated as such without naming their components.

(ii) Color additives may be designated as coloring without naming specific color components unless the naming of such components is required by a color additive regulation prescribed in subchapter A of this chapter.

(iii) Trace amounts of harmless substances added solely for individual product identification need not be named. If it is intended for administration by parenteral injection, the quantity or proportion of all inactive ingredients, except that ingredients added to adjust the pH or to make the drug isotonic may be declared by name and a statement of their effect; and if the vehicle is water for injection it need not be named.

(6) An identifying lot or control number from which it is possible to determine the complete manufacturing history of the package of the drug.

(7) A statement directed to the pharmacist specifying the type of container to be used in dispensing the drug product to maintain its identity, strength, quality, and purity. Where there are standards and test procedures for determining that the container meets the requirements for specified types of containers as defined in an official compendium, such terms may be used. For example, ''Dispense in tight, light-resistant container as defined in the National Formulary''. Where standards and test procedures for determining the types of containers to be used in dispensing the drug product are not included in an official compendium, the specific container or types of containers known to be adequate to maintain the identity, strength, quality, and purity of the drug products shall be described. For example, ''Dispense in containers which (statement of specifications which clearly enable the dispensing pharmacist to select an adequate container)'': *Provided, however,* That in the case of containers too small or otherwise unable to accommodate a label with sufficient space to bear all such information, but which are packaged within an outer container from which they are removed for dispensing or use, the information required by paragraph (b) (2), (3), (5), and (7) of this section may be contained in other labeling on or within the package from which it is to be dispensed; the information referred to in paragraph (b)(1) of this section may be placed on such outer container only; and the information required by paragraph (b)(6) of this section may be on the crimp of the dispensing tube. The information required by this paragraph (b)(7) is not required for prescription drug products packaged in unit-dose, unit-of-use, on other packaging format in which the manufacturer's original package is designed and intended to be dispensed to patients without repackaging.