

associated with the product without indicating each active ingredient (the established name and quantity of each active ingredient are not required); the dosage form; and the price charged for a prescription for a specific quantity of the drug product.

(3) The reminder advertisement or reminder labeling may also include other written, printed, or graphic matter, e.g., identification of professional or convenience services provided by the pharmacy: *Provided*, That such information is neither false nor misleading and contains no representation or suggestion concerning the drug product's safety, effectiveness, or indications for use.

(4) The price stated in the reminder advertisement or reminder labeling as that charged for a prescription shall include all charges to the consumer including, but not limited to, the cost of the drug product, professional fees, and handling fees, if any. Mailing fees and delivery fees, if any, may be stated separately and without repetition.

(b) This exemption from §§ 201.100 and 202.1 of this chapter is applicable to all prescription drug reminder labeling and reminder advertisements solely intended to provide consumers with information regarding the price charged for prescriptions including price lists, catalogs, and other promotional material, whether mailed, posted in a pharmacy, placed in a newspaper, or aired on radio or television.

(c) Any reminder advertisement or reminder labeling intended to provide consumers with prescription price information which is not in compliance with this section shall be the subject of appropriate regulatory action. Such action may be taken against the product and/or the responsible person.

[40 FR 58799, Dec. 18, 1975]

PART 201—LABELING

Subpart A—General Labeling Provisions

Sec.

- 201.1 Drugs; name and place of business of manufacturer, packer, or distributor.
- 201.2 Drugs and devices; National Drug Code numbers.
- 201.5 Drugs; adequate directions for use.
- 201.6 Drugs; misleading statements.
- 201.10 Drugs; statement of ingredients.

- 201.15 Drugs; prominence of required label statements.
- 201.16 Drugs; Spanish-language version of certain required statements.
- 201.17 Drugs; location of expiration date.
- 201.18 Drugs; significance of control numbers.
- 201.19 Drugs; use of term “infant”.
- 201.20 Declaration of presence of FD&C Yellow No. 5 and/or FD&C Yellow No. 6 in certain drugs for human use.
- 201.21 Declaration of presence of phenylalanine as a component of aspartame in over-the-counter and prescription drugs for human use.
- 201.22 Prescription drugs containing sulfites; required warning statements.
- 201.23 Required pediatric studies.
- 201.24 Labeling for systemic antibacterial drug products.
- 201.25 Bar code label requirements.

Subpart B—Labeling Requirements for Prescription Drugs and/or Insulin

- 201.50 Statement of identity.
- 201.51 Declaration of net quantity of contents.
- 201.55 Statement of dosage.
- 201.56 General requirements on content and format of labeling for human prescription drugs.
- 201.57 Specific requirements on content and format of labeling for human prescription drugs.
- 201.58 Requests for waiver of requirement for adequate and well-controlled studies to substantiate certain labeling statements.
- 201.59 Effective date of §§ 201.56, 201.57, 201.100(d)(3), and 201.100(e).

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

- 201.60 Principal display panel.
- 201.61 Statement of identity.
- 201.62 Declaration of net quantity of contents.
- 201.63 Pregnancy/breast-feeding warning.
- 201.64 Sodium labeling.
- 201.66 Format and content requirements for over-the-counter (OTC) drug product labeling.
- 201.70 Calcium labeling.
- 201.71 Magnesium labeling.
- 201.72 Potassium labeling.

Subpart D—Exemptions From Adequate Directions for Use

- 201.100 Prescription drugs for human use.
- 201.105 Veterinary drugs.
- 201.115 New drugs or new animal drugs.
- 201.116 Drugs having commonly known directions.
- 201.117 Inactive ingredients.

Food and Drug Administration, HHS

§ 201.1

- 201.119 In vitro diagnostic products.
- 201.120 Prescription chemicals and other prescription components.
- 201.122 Drugs for processing, repackaging, or manufacturing.
- 201.125 Drugs for use in teaching, law enforcement, research, and analysis.
- 201.127 Drugs; expiration of exemptions.
- 201.128 Meaning of "intended uses".
- 201.129 Drugs; exemption for radioactive drugs for research use.

Subpart E—Other Exemptions

- 201.150 Drugs; processing, labeling, or repackaging.
- 201.161 Carbon dioxide and certain other gases.

Subpart F—Labeling Claims for Drugs in Drug Efficacy Study

- 201.200 Disclosure of drug efficacy study evaluations in labeling and advertising.

Subpart G—Specific Labeling Requirements for Specific Drug Products

- 201.300 Notice to manufacturers, packers, and distributors of glandular preparations.
- 201.301 Notice to manufacturers, packers, and distributors of estrogenic hormone preparations.
- 201.302 Notice to manufacturers, packers, and distributors of drugs for internal use which contain mineral oil.
- 201.303 Labeling of drug preparations containing significant proportions of wintergreen oil.
- 201.304 Tannic acid and barium enema preparations.
- 201.305 Isoproterenol inhalation preparations (pressurized aerosols, nebulizers, powders) for human use; warnings.
- 201.306 Potassium salt preparations intended for oral ingestion by man.
- 201.307 Sodium phosphates; package size limitation, warnings, and directions for over-the-counter sale.
- 201.308 Ipecac syrup; warnings and directions for use for over-the-counter sale.
- 201.309 Acetophenetidin (phenacetin)-containing preparations; necessary warning statement.
- 201.310 Phenindione; labeling of drug preparations intended for use by man.
- 201.311 [Reserved]
- 201.312 Magnesium sulfate heptahydrate; label declaration on drug products.
- 201.313 Estradiol labeling.
- 201.314 Labeling of drug preparations containing salicylates.
- 201.315 Over-the-counter drugs for minor sore throats; suggested warning.
- 201.316 Drugs with thyroid hormone activity for human use; required warning.

- 201.317 Digitalis and related cardiotonic drugs for human use in oral dosage forms; required warning.
- 201.319 Water-soluble gums, hydrophilic gums, and hydrophilic mucilloids (including, but not limited to agar, alginic acid, calcium polycarbophil, carboxymethylcellulose sodium, carrageenan, chondrus, glucomannan ((B-1,4 linked) polymannose acetate), guar gum, karaya gum, kelp, methylcellulose, plantago seed (psyllium), polycarbophil tragacanth, and xanthan gum) as active ingredients; required warnings and directions.
- 201.320 Warning statements for drug products containing or manufactured with chlorofluorocarbons or other ozone-depleting substances.
- 201.322 Over-the-counter drug products containing internal analgesic/antipyretic active ingredients; required alcohol warning.
- 201.323 Aluminum in large and small volume parenterals used in total parenteral nutrition.

APPENDIX A TO PART 201—EXAMPLES OF GRAPHIC ENHANCEMENTS USED BY FDA

AUTHORITY: 21 U.S.C. 321, 331, 351, 352, 353, 355, 358, 360, 360b, 360gg–360ss, 371, 374, 379e; 42 U.S.C. 216, 241, 262, 264.

SOURCE: 40 FR 13998, Mar. 27, 1975, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 201 appear at 69 FR 13717, Mar. 24, 2004.

Subpart A—General Labeling Provisions

§ 201.1 Drugs; name and place of business of manufacturer, packer, or distributor.

(a) A drug or drug product (as defined in § 320.1 of this chapter) in finished package form is misbranded under section 502 (a) and (b)(1) of the act if its label does not bear conspicuously the name and place of business of the manufacturer, packer, or distributor. This paragraph does not apply to any drug or drug product dispensed in accordance with section 503(b)(1) of the act.

(b) As used in this section, and for purposes of section 502 (a) and (b)(1) of the act, the manufacturer of a drug product is the person who performs all of the following operations that are required to produce the product: (1) Mixing, (2) granulating, (3) milling, (4) molding, (5) lyophilizing, (6) tableting,

§201.1

(7) encapsulating, (8) coating, (9) sterilizing, and (10) filling sterile, aerosol, or gaseous drugs into dispensing containers.

(c) If no person performs all of the applicable operations listed in paragraph (b) of this section, no person may be represented as manufacturer except as follows:

(1) If the person performs more than one half of the applicable operations listed in paragraph (b) of this section and acknowledges the contribution of other persons who have performed the remaining applicable operations by stating on the product label that "Certain manufacturing operations have been performed by other firms."; or

(2) If the person performs at least one applicable operation listed in paragraph (b) of this section and identifies by appropriate designation all other persons who have performed the remaining applicable operations, e.g., "Made by (Person A), Filled by (Person B), Sterilized by (Person C)"; or

(3) If the person performs at least one applicable operation listed in paragraph (b) of this section and the person is listed along with all other persons who have performed the remaining applicable operations as "joint manufacturers." A list of joint manufacturers shall be qualified by the phrase "Jointly Manufactured By _____," and the names of all of the manufacturers shall be printed together in the same type size and style; or

(4) If the person performs all applicable operations listed in paragraph (b) of this section except for those operations listed in paragraph (d) of this section. For purposes of this paragraph, person, when it identifies a corporation, includes a parent, subsidiary, or affiliate company where the related companies are under common ownership and control.

(d) The Food and Drug Administration finds that it is the common practice in the drug industry to contract out the performance of certain manufacturing operations listed in paragraph (b) of this section. These operations include: (1) Soft-gelatin encapsulating, (2) aerosol filling, (3) sterilizing by irradiation, (4) lyophilizing, and (5) ethylene oxide sterilization.

21 CFR Ch. I (4-1-04 Edition)

(e) A person performs an operation listed in paragraph (b) of this section only if the operation is performed, including the performance of the appropriate in-process quality control operations, except laboratory testing of samples taken during processing, as follows:

(1) By individuals, a majority of whom are employees of the person and, throughout the performance of the operation, are subject to the person's direction and control;

(2) On premises that are continuously owned or leased by the person and subject to the person's direction and control; and

(3) On equipment that is continuously owned or leased by the person. As used in this paragraph, person, when it identifies a corporation, includes a parent, subsidiary, or affiliate company where the related companies are under common ownership and control.

(f) The name of the person represented as manufacturer under paragraph (b) or (c) of this section must be the same as either (1) the name of the establishment (as defined in §207.3(b) of this chapter) under which that person is registered at the time the labeled product is produced or (2) the registered establishment name of a parent, subsidiary, or affiliate company where the related companies are under common ownership and control. In addition, the name shall meet the requirements of paragraph (g) of this section.

(g) The requirement for declaration of the name of the manufacturer, packer, or distributor shall be deemed to be satisfied, in the case of a corporate person, only by the actual corporate name, except that the corporate name may be the name of a parent, subsidiary, or affiliate company where the related companies are under common ownership and control. The corporate name may be preceded or followed by the name of the particular division of the corporation. "Company," "Incorporated," etc., may be abbreviated or omitted and "The" may be omitted. In the case of an individual, partnership, or association, the name under which the business is conducted shall be used.

(h)(1) Except as provided in this section, no person other than the manufacturer, packer, or distributor may be identified on the label of a drug or drug product.

(2) The appearance on a drug product label of a person's name without qualification is a representation that the named person is the sole manufacturer of the product. That representation is false and misleading, and the drug product is misbranded under section 502(a) of the act, if the person is not the manufacturer of the product in accordance with this section.

(3) If the names of two or more persons appear on the label of a drug or drug product, the label may identify which of the persons is to be contacted for further information about the product.

(4) If a trademark appears on the drug or drug product label or appears as a mark directly on the drug product (e.g., tablet or capsule), the label may identify the holder or licensee of the trademark. The label may also state whether the person identified holds the trademark or is licensee of the trademark.

(5) If the distributor is named on the label, the name shall be qualified by one of the following phrases: "Manufactured for _____", "Distributed by _____", "Manufactured by _____ for _____", "Manufactured for _____ by _____", "Distributor: _____", "Marketed by _____". The qualifying phrases may be abbreviated.

(6) If the packer is identified on the label, the name shall be qualified by the phrase "Packed by _____" or "Packaged by _____". The qualifying phrases may be abbreviated.

(i) The statement of the place of business shall include the street address, city, State, and ZIP Code. For a foreign manufacturer, the statement of the place of business shall include the street address, city, country, and any applicable mailing code. The street address may be omitted if it is shown in a current city directory or telephone directory. The requirement for inclusion of the ZIP Code shall apply to consumer commodity labels developed or revised after July 1, 1969. In the case of nonconsumer packages, the ZIP Code

shall appear either on the label or the labeling (including the invoice).

(j) If a person manufactures, packs, or distributes a drug or drug product at a place other than the person's principal place of business, the label may state the principal place of business in lieu of the actual place where such drug or drug product was manufactured or packed or is to be distributed, unless such statement would be misleading.

(k) Paragraphs (b), (c), (d), (e), and (f) of this section, do not apply to the labeling of drug components.

(l) A drug product is misbranded under section 502(a) of the act if its labeling identifies a person as manufacturer, packer, or distributor, and that identification does not meet the requirements of this section.

(m) This section does not apply to biological drug products that are subject to the requirements of section 351 of the Public Health Service Act, 42 U.S.C. 262.

[45 FR 25775, Apr. 15, 1980; 45 FR 72118, Oct. 31, 1980, as amended at 48 FR 37620, Aug. 19, 1983]

§ 201.2 Drugs and devices; National Drug Code numbers.

The National Drug Code (NDC) number is requested but not required to appear on all drug labels and in all drug labeling, including the label of any prescription drug container furnished to a consumer. If the NDC number is shown on a drug label, it shall be displayed as required in § 207.35(b)(3) of this chapter.

[40 FR 52002, Nov. 7, 1975]

§ 201.5 Drugs; adequate directions for use.

Adequate directions for use means directions under which the layman can use a drug safely and for the purposes for which it is intended. (Section 201.128 defines "intended use.") Directions for use may be inadequate because, among other reasons, of omission, in whole or in part, or incorrect specification of:

(a) Statements of all conditions, purposes, or uses for which such drug is intended, including conditions, purposes, or uses for which it is prescribed, recommended, or suggested in its oral, written, printed, or graphic advertising, and conditions, purposes, or