

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

- 201.50 Statement of identity.
- 201.51 Declaration of net quantity of contents.
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- 201.56 Requirements on content and format of labeling for human prescription drug and biological products.
- 201.57 Specific requirements on content and format of labeling for human prescription drug and biological products described in § 201.56(b)(1).
- 201.58 Waiver of labeling requirements.

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

- 201.60 Principal display panel.
- 201.61 Statement of identity.
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- 201.63 Pregnancy/breast-feeding warning.
- 201.64 Sodium labeling.
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- 201.70 Calcium labeling.
- 201.71 Magnesium labeling.
- 201.72 Potassium labeling.
- 201.80 Specific requirements on content and format of labeling for human prescription drug and biological products; older drugs not described in § 201.56(b)(1).

Subpart D—Exemptions From Adequate Directions for Use

- 201.100 Prescription drugs for human use.
- 201.105 Veterinary drugs.
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- 201.116 Drugs having commonly known directions.
- 201.117 Inactive ingredients.
- 201.119 In vitro diagnostic products.
- 201.120 Prescription chemicals and other prescription components.
- 201.122 Drugs for processing, repacking, 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 repacking.
- 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.
- 201.323 Aluminum in large and small volume parenterals used in total parenteral nutrition.
- 201.325 Over-the-counter drugs for vaginal contraceptive and spermicide use containing nonoxynol 9 as the active ingredient; required warnings and labeling information.
- 201.326 Over-the-counter drug products containing internal analgesic/antipyretic active ingredients; required warnings and other labeling.
- 201.327 Over-the-counter sunscreen drug products; required labeling based on effectiveness testing.

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