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 201.21 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.
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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.
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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 throat; 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, alginitic acid, calcium polycarboxylate, carboxymethylcellulose sodium, carrageenan, chondrus, glucomannan ((B-1,4 linked) polymannose acetate), guar gum, karaya gum, kelp, methylcellulose, plantago seed (psyllium), polycarboxylate 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.
201.321 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


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


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