

or intended for ophthalmic use, including preparations for cleansing the eyes, should be sterile. It is further evident that such preparations purport to be of such purity and quality as to be suitable for safe use in the eye.

(2) The Food and Drug Administration concludes that all such preparations, if they are not sterile, fall below their professed standard of purity or quality and may be unsafe. In a statement of policy issued on September 1, 1964, the Food and Drug Administration ruled that liquid preparations offered or intended for ophthalmic use that are not sterile may be regarded as adulterated within the meaning of section 501(c) of the Federal Food, Drug, and Cosmetic Act (the act), and, further, may be deemed misbranded within the meaning of section 502(j) of the act. This ruling is extended to affect all preparations for ophthalmic use. By this regulation, this ruling is applicable to ophthalmic preparations that are regulated as drugs. By the regulation in § 800.10 of this chapter, this ruling is applicable to ophthalmic preparations that are regulated as medical devices.

(3) The containers of ophthalmic preparations shall be sterile at the time of filling and closing, and the container or individual carton shall be so sealed that the contents cannot be used without destroying the seal. The packaging and labeling of ophthalmic preparations that are over-the-counter drugs shall also comply with § 211.132 of this chapter on tamper-resistant packaging requirements.

(b) Liquid ophthalmic preparations packed in multiple-dose containers should:

(1) Contain one or more suitable and harmless substances that will inhibit the growth of microorganisms; or

(2) Be so packaged as to volume and type of container and so labeled as to duration of use and with such necessary warnings as to afford adequate protection and minimize the hazard of injury resulting from contamination during use.

(c) Eye cups, eye droppers, and other dispensers intended for ophthalmic use should be sterile, and may be regarded as falling below their professed standard of purity or quality if they are not

sterile. These articles, which are regulated as drugs if packaged with the drugs with which they are to be used, should be packaged so as to maintain sterility until the package is opened and be labeled, on or within the retail package, so as to afford adequate directions and necessary warnings to minimize the hazard of injury resulting from contamination during use.

[40 FR 13996, Mar. 27, 1975, as amended at 47 FR 50455, Nov. 5, 1982]

§ 200.51 Aqueous-based drug products for oral inhalation.

(a) All aqueous-based drug products for oral inhalation must be manufactured to be sterile.

(b) Manufacturers must also comply with the requirements in § 211.113(b) of this chapter.

[65 FR 34089, May 26, 2000]

Subpart D [Reserved]

Subpart E—Prescription Drug Consumer Price Listing

§ 200.200 Prescription drugs; reminder advertisements and reminder labeling to provide price information to consumers.

(a) Prescription drug reminder advertisements and reminder labeling intended to provide price information to consumers are exempt from the requirements of §§ 201.100 and 202.1 of this chapter if all of the following conditions are met:

(1) The only purpose of the reminder advertisement or reminder labeling is to provide consumers with information concerning the price charged for a prescription for a particular drug product, and the reminder advertisement or reminder labeling contains no representation or suggestion concerning the drug product's safety, effectiveness, or indications for use.

(2) The reminder advertisement or reminder labeling contains the proprietary name of the drug product, if any; the established (generic) name of the drug product, if any; the drug product's strength if the product contains a single active ingredient or if the product contains more than one active ingredient and a relevant strength can be

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.

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.

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.
- 201.119 In vitro diagnostic products.
- 201.120 Prescription chemicals and other prescription components.