

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