

(c) *Exemption from the general accidental overdose warning.* The labeling for antifatulent drug products containing simethicone identified in § 332.10 and antacid/antiflatulent combination drug products provided for in § 332.15, containing the active ingredients identified in § 331.11(a), (b), and (d) through (m) of this chapter are exempt from the requirement in § 330.1(g) of this chapter that the labeling bear the general warning statement “In case of accidental overdose, seek professional assistance or contact a poison control center immediately.” The labeling must continue to bear the first part of the general warning in § 330.1(g) of this chapter, which states, “Keep this and all drugs out of the reach of children.”

[39 FR 19877, June 4, 1974, as amended at 40 FR 11719, Mar. 13, 1975; 51 FR 16266, May 1, 1986; 51 FR 27763, Aug. 1, 1986; 52 FR 7830, Mar. 13, 1987; 61 FR 8838, Mar. 5, 1996]

§ 332.31 Professional labeling.

(a) The labeling of the product provided to health professionals (but not to the general public) may contain as additional indications postoperative gas pain or for use in endoscopic examination.

(b) Professional labeling for an anti-flatulent-antacid combination may contain information allowed for health professionals for antacids and anti-flatulents.

PART 333—TOPICAL ANTI-MICROBIAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A [Reserved]

Subpart B—First Aid Antibiotic Drug Products

Sec.

- 333.101 Scope.
- 333.103 Definitions.
- 333.110 First aid antibiotic active ingredients.
- 333.120 Permitted combinations of active ingredients.
- 333.150 Labeling of first aid antibiotic drug products.
- 333.160 Labeling of permitted combinations of active ingredients.

Subpart C—Topical Antifungal Drug Products

- 333.201 Scope.
- 333.203 Definitions.
- 333.210 Antifungal active ingredients.
- 333.250 Labeling of antifungal drug products.
- 333.280 Professional labeling.

Subpart D—Topical Acne Drug Products

- 333.301 Scope.
- 333.303 Definitions.
- 333.310 Acne active ingredients.
- 333.320 Permitted combinations of active ingredients.
- 333.350 Labeling of acne drug products.

AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

SOURCE: 52 FR 47322, Dec. 11, 1987, unless otherwise noted.

Subpart A [Reserved]

Subpart B—First Aid Antibiotic Drug Products

§ 333.101 Scope.

(a) An over-the-counter first aid antibiotic drug product in a form suitable for topical administration is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this subpart and each of the general conditions established in § 330.1.

(b) References in this subpart to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§ 333.103 Definitions.

As used in this subpart:

First aid antibiotic. An antibiotic-containing drug product applied topically to the skin to help prevent infection in minor cuts, scrapes, and burns.

[52 FR 47322, Dec. 11, 1987, as amended at 64 FR 403, Jan. 5, 1999]

§ 333.110 First aid antibiotic active ingredients.

The product consists of any of the following active ingredients within the specified concentration established for each ingredient and in the specified dosage form: