Subpart C—Labeling

§ 332.30 Labeling of antiflatulent products.

(a) Statement of identity. The labeling of the product contains the established name of the drug, if any, and identifies the product as an “antiflatulent,” “antigas,” or “antiflatulent (antigas).”

(b) Indications. The labeling of the product states, under the heading “Indications,” one or more of the phrases listed in this paragraph (b), as appropriate. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in this paragraph (b), may also be used, as provided in §330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) (Select one of the following: "Alleviates or Relieves") "the symptoms referred to as gas."

(2) (Select one of the following: "Alleviates" or "Relieves") (select one or more of the following: "bloating,” “pressure,” “fullness,” or “stuffed feeling”) “commonly referred to as gas.”

(c) Exemption from the general accidental overdose warning. The labeling for antiflatulent 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.”

Subpart B—Active Ingredients

§ 332.10 Antiflatulent active ingredients.

Simethicone; maximum daily dose 500 mg. There is no dosage limitation at this time for professional labeling.

§ 332.15 Combination with non-antiflatulent active ingredients.

An antiflatulent may contain any generally recognized as safe and effective antacid ingredient(s) if it is indicated for use solely for the concurrent symptoms of gas associated with heartburn, sour stomach or acid indigestion.

Subpart C—Labeling

§ 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 antiflatulent-antacid combination may
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contain information allowed for health professionals for antacids and anti-flatulents.

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

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.

§ 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:

(a) Bacitracin ointment containing, in each gram, 500 units of bacitracin in a suitable ointment base.

(b) Bacitracin zinc ointment containing, in each gram, 500 units of bacitracin zinc in a suitable ointment base.

(c) Chlortetracycline hydrochloride ointment containing, in each gram, 30 milligrams of chlortetracycline hydrochloride in a suitable ointment base.

(d) Neomycin sulfate ointment containing, in each gram, 3.5 milligrams of neomycin in a suitable water soluble or oleaginous ointment base.

(e) Neomycin sulfate cream containing, in each gram, 3.5 milligrams of neomycin in a suitable cream base.

(f) Tetracycline hydrochloride ointment containing, in each gram, 30 milligrams of tetracycline hydrochloride in a suitable ointment base.


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

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.


§ 333.120 Permitted combinations of active ingredients.

The following combinations are permitted provided each active ingredient is present within the established concentration and in the specified dosage form, and the product is labeled in accordance with §333.160.

(a) Combinations of antibiotic active ingredients. (1) Bacitracin-neomycin sulfate ointment containing, in each gram, 500 units of bacitracin and 3.5