

the active ingredients identified in §331.11(a), (b), and (d) through (m); permitted combinations of these ingredients provided for in §331.10; and any of these ingredients or combinations of these ingredients in combination with simethicone (identified in §332.10 of this chapter and provided for in §331.15(c)), 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.” With the exception of sodium bicarbonate powder products identified in §331.11(k)(1), 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.”

(g) [Reserved]

(h) The word “doctor” may be substituted for the word “physician” in any of the labeling statements in this section.

[39 FR 19874, June 4, 1974, as amended at 47 FR 38484, Aug. 31, 1982; 51 FR 16266, May 1, 1986; 51 FR 27763, Aug. 1, 1986; 52 FR 7830, Mar. 13, 1987; 55 FR 11581, Mar. 29, 1990; 58 FR 45208, Aug. 26, 1993; 59 FR 60556, Nov. 25, 1994; 61 FR 17806, Apr. 22, 1996; 64 FR 13295, Mar. 17, 1999; 69 FR 13734, Mar. 24, 2004]

#### §331.80 Professional labeling.

(a) The labeling of the product provided to health professionals (but not to the general public):

(1) Shall contain the neutralizing capacity of the product as calculated using the procedure set forth in United States Pharmacopeia 23/National Formulary 18 expressed in terms of the dosage recommended per minimum time interval or, if the labeling recommends more than one dosage, in terms of the minimum dosage recommended per minimum time interval.

(2) May contain an indication for the symptomatic relief of hyperacidity associated with the diagnosis of peptic ulcer, gastritis, peptic esophagitis, gastric hyperacidity, and hiatal hernia.

(3) *For products containing basic aluminum carbonate gel identified in §331.11(a)(1)—Indication.* “For the treatment, control, or management of hyperphosphatemia, or for use with a

low phosphate diet to prevent formation of phosphate urinary stones, through the reduction of phosphates in the serum and urine.”

(4) *For products containing aluminum identified in §331.11(a)—Warnings.* (i) Prolonged use of aluminum-containing antacids in patients with renal failure may result in or worsen dialysis osteomalacia. Elevated tissue aluminum levels contribute to the development of the dialysis encephalopathy and osteomalacia syndromes. Small amounts of aluminum are absorbed from the gastrointestinal tract and renal excretion of aluminum is impaired in renal failure. Aluminum is not well removed by dialysis because it is bound to albumin and transferrin, which do not cross dialysis membranes. As a result, aluminum is deposited in bone, and dialysis osteomalacia may develop when large amounts of aluminum are ingested orally by patients with impaired renal function.

(ii) Aluminum forms insoluble complexes with phosphate in the gastrointestinal tract, thus decreasing phosphate absorption. Prolonged use of aluminum-containing antacids by normophosphatemic patients may result in hypophosphatemia if phosphate intake is not adequate. In its more severe forms, hypophosphatemia can lead to anorexia, malaise, muscle weakness, and osteomalacia.

(b) Professional labeling for an antacid-antiflatulent combination may contain the information allowed for health professionals for antacids and antiflatulents.

[39 FR 19874, June 4, 1974. Redesignated and amended at 55 FR 19859, May 11, 1990]

## PART 332—ANTIFLATULENT PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

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

SOURCE: 39 FR 19877, June 4, 1974, unless otherwise noted.

**Subpart A—General Provisions****§ 332.1 Scope.**

An over-the-counter antifatulent product in a form suitable for oral administration is generally recognized as safe and effective and is not misbranded if it meets each of the following conditions and each of the general conditions established in § 330.1 of this chapter.

**§ 332.3 Definitions.**

As used in this part:

*Antigas.* A term that may be used interchangeably with the term antifatulent. Neither term should be considered as describing the mechanism of action of the active ingredient contained in the product.

[61 FR 8838, Mar. 5, 1996]

**Subpart B—Active Ingredients****§ 332.10 Antifatulent active ingredients.**

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

**§ 332.15 Combination with non-antifatulent active ingredients.**

An antifatulent 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****§ 332.30 Labeling of antifatulent drug 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 “antifatulent,” “antigas,” or “antifatulent (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 antifatulent drug products containing simethicone identified in § 332.10 and antacid/antifatulent 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 antifatulent-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]**

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- 333.310 Acne active ingredients.
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- 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:

(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.

[52 FR 47322, Dec. 11, 1987, as amended at 53 FR 18838, May 25, 1988; 64 FR 403, Jan. 5, 1999]

**§ 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