

**Subpart C—Labeling**

332.30 Labeling of antifatulent products.  
332.31 Professional labeling.

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