U.S. Food and Drug Administration

Final Administrative Order (OTC000001)

Over-the-Counter Monograph M002: Antiflatulent Products for Over-the-Counter Human Use (Posted September 20, 2021)

I. Summary

Over-the-Counter Monograph M002: Antiflatulent Products for Over-the-Counter Human Use, as set forth in this document, is a final administrative order (final order) deemed by section 505G(b)(8) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355h(b)(8)), and effective upon enactment of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Public Law 116-136, on March 27, 2020.

II. Background

The CARES Act added section 505G of the FD&C Act, which revised the framework for the regulation of over-the-counter (OTC) monograph drug products. Among other things, section 505G of the FD&C Act provides as a baseline status that, as of the date of enactment of the CARES Act, drugs that satisfy certain requirements described in section 505G(a)(1) or (2) are deemed to be generally recognized as safe and effective under section 201(p)(1) of the FD&C Act (21 U.S.C. 321(p)(1)), not a new drug under section 201(p), and not subject to section 503(b)(1) of the FD&C Act (21 U.S.C. 353(b)(1)). To obtain this status, among other things, a drug either must be one that is in conformity with the requirements for nonprescription use of a final monograph issued under part 330 (21 CFR part 330) (except as provided in section 505G(a)(2)),[1] as well as other requirements,[2] or must be one that is (i) classified in category I for safety and effectiveness under a tentative final monograph that is the most recently applicable proposal or determination issued under part 330, and (ii) in conformity with the proposed requirements for nonprescription use of such tentative final monograph and any applicable subsequent determination by the Secretary, as well as other requirements.[3] Other applicable requirements in section 505G(a)(1) of the FD&C Act include conditions or requirements under section 505G(b) of the FD&C Act.

Complementary to the requirements for conformity to tentative final or final monographs described in section 505G(a)(1) and (2) of the FD&C Act, Congress provided that, under section 505G(b)(8) of the FD&C Act, a final monograph or tentative final monograph that establishes

[1] Section 505G(a)(2) of the FD&C Act is inapplicable here. It establishes the applicable requirements in terms of conformity with a final monograph, for purposes of section 505G(a)(1)(A)(i) of the FD&C Act, for sunscreen drugs subject to section 505G of the FD&C Act.
[2] Section 505G(a)(1)(A) of the FD&C Act.
[3] Section 505G(a)(1)(B) of the FD&C Act.

conditions of use for a drug described in section 505G(a)(1) or (2) and that represents the most recently promulgated version of the conditions of use, including as modified, in whole or in part, by any proposed or final rule, is deemed to be a final order. The final order may be amended, revoked, or otherwise modified in accordance with the procedures under section 505G of the FD&C Act. Under section 505G(b)(8)(C) of the FD&C Act, the deemed establishment of a final order is construed to include technical amendments necessary to ensure that the order is appropriately harmonized, in terms of terminology or cross-references, with the applicable provisions of the FD&C Act (and regulations) and any other final orders issued under section 505G of the FD&C Act.

In the *Federal Register* of June 4, 1974 (39 FR 19862 at 19874), FDA issued a final OTC monograph under the procedure in part 330, establishing conditions under which OTC antiflatulent drug products are generally recognized as safe and effective (GRASE). This final OTC monograph was codified in 21 CFR part 332 and subsequently amended by final rules issued on March 13, 1975 (40 FR 11718 at 11719), May 1, 1986 (51 FR 16258 at 16266), August 1, 1986 (51 FR 27762 at 27763), March 13, 1987 (52 FR 7830), and March 5, 1996 (61 FR 8836 at 8838).

Accordingly, this final order for OTC antiflatulent products incorporates the requirements of the final monograph for OTC antiflatuent products issued under part 330, as codified in part 332 as of March 27, 2020, with technical amendments, including consolidating professional use provisions into their own part.

III. Final Administrative Order

Over-the-Counter Monograph M002:
Antiflatulent Products for Over-the-Counter Human Use

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

Part A—General Provisions

§ M002.1 Scope

An over-the-counter (OTC) antiflatulent 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 21 CFR 330.1.

§ M002.3 Definitions

As used in this OTC monograph:

Antigas. A term that may be used interchangeably with the term antiflatulent. 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]

Part B—Active Ingredients

§ M002.10 Antiflatulent active ingredients

Simethicone; maximum daily dose 500 mg.

§ M002.15 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.

Part C—Labeling

§ M002.30 Labeling of antiflatulent 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 “antiflatulent,” “antigas,” or “antiflatulent (antigas).”

(b) Indications. The labeling of the product states, under the heading “Uses,” one or more of the phrases listed in § M002.30(b), as appropriate. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in § M002.30(b), may also be used, as provided in 21 CFR 330.1(c)(2), subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 352) relating to misbranding and the prohibition in section 301(d) of the FD&C Act (21 U.S.C. 331(d)) against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the FD&C Act (21 U.S.C. 355(a)).

(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 § M002.10 and antacid/antiflatulent combination drug products provided for in § M002.15, containing the active ingredients identified in § M001.11(a), (b), and (d) through (m) of OTC Monograph M001 are exempt from the requirement in 21 CFR 330.1(g) 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 21 CFR 330.1(g), 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]

Part D—Professional Use

§ M002.31 Antiflatulent active ingredients for professional use

Simethicone; There is no dosage limitation at this time for professional labeling.

§ M002.32 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 contain information allowed for health professionals for antacids and antiflatulents.