U.S. Food and Drug Administration

Final Administrative Order (OTC000016)

Over-the-Counter Monograph M026: Deodorant Drug Products for Internal Use for Over-the-Counter Human Use (Posted November 23, 2021)

I. Summary

Over-the-Counter Monograph M026: Deodorant Drug Products for Internal Use 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 May 11, 1990 (55 FR 19862 at 19865), FDA issued a final OTC monograph under the procedure in part 330, establishing conditions under which OTC deodorant drug products for internal use are generally recognized as safe and effective (GRASE). This final OTC monograph was codified in 21 CFR part 357, subpart I.

Accordingly, this final order for OTC deodorant drug products for internal use incorporates the requirements of the final monograph for OTC deodorant products for internal use issued under part 330, as codified in part 357, subpart I as of March 27, 2020, with technical amendments.

III. Final Administrative Order

Over-the-Counter Monograph M026:
Deodorant Drug Products for Internal Use for Over-the-Counter Human Use

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SOURCE: 55 FR 19865, May 11, 1990, unless otherwise noted.

Part A—General Provisions

§ M026.1 Scope

An over-the-counter (OTC) deodorant drug product for internal use in a form suitable for oral administration is generally recognized as safe and effective and is not misbranded if it meets each condition in this OTC monograph and each general condition established in 21 CFR 330.1.

§ M026.3 Definitions

As used in this OTC monograph:

(a) Colostomy. An external operative opening of the colon.

(b) Deodorant for internal use. An ingredient taken internally to reduce odors arising from conditions such as colostomies, ileostomies, or fecal incontinence.

(c) Ileostomy. An external operative opening from the ileum.

(d) Incontinence. An inability to retain urine or feces.

Part B—Active Ingredients

§ M026.10 Active ingredients for deodorant drug products for internal use

The active ingredient of the product consists of either of the following when used within the dosage limits established for each ingredient in § M026.50(d):

(a) Bismuth subgallate.

(b) Chlorophyllin copper complex.

Part C—Labeling

§ M026.50 Labeling of deodorant drug products for internal use

(a) Statement of identity. The labeling of the product contains the established name of the drug, if any, and identifies the product as a “deodorant for internal use” or as a “colostomy or ileostomy deodorant.”

(b) Indications. The labeling of the product states, under the heading "Uses," any of the phrases listed in § M026.50(b) as appropriate. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in § M026.50(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) For products containing bismuth subgallate identified in § M026.10(a). "An aid to reduce odor from a colostomy or ileostomy."

(2) For products containing chlorophyllin copper complex identified in § M026.10(b).

(i) "An aid to reduce odor from a colostomy or ileostomy."

(ii) "An aid to reduce fecal odor due to incontinence."

(c) Warnings. For products containing chlorophyllin copper complex identified in § M026.10(b), the labeling of the product contains the following warnings under the heading "Warnings":

(1) "If cramps or diarrhea occurs, reduce the dosage. If symptoms persist, consult your doctor."

(2) The warning required by 21 CFR 330.1(g) concerning overdose is not required on products containing chlorophyllin copper complex identified in § M026.10(b).

(d) Directions. The labeling of the product contains the following information under the heading "Directions."

(1) For products containing bismuth subgallate identified in § M026.10(a). Adults and children 12 years of age and over: Oral dosage is 200 to 400 milligrams up to 4 times daily. Children under 12 years of age: consult a doctor.

(2) For products containing chlorophyllin copper complex identified in § M026.10(b). Adults and children 12 years of age and over: Oral dosage is 100 to 200 milligrams daily in divided doses as required. If odor is not controlled, take up to an additional 100 milligrams daily in divided doses as required. The smallest effective dose should be used. Do not exceed 300 milligrams daily. Children under 12 years of age: consult a doctor.