U.S. Food and Drug Administration

Final Administrative Order (OTC000002)

Over-the-Counter Monograph M010: Nighttime Sleep-Aid Drug Products for Over-the-Counter Human Use (Posted September 20, 2021)

I. Summary

Over-the-Counter Monograph M010: Nighttime Sleep-Aid Drug 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 February 14, 1989 (54 FR 6814 at 6826), FDA issued a final OTC monograph under the procedure in part 330, establishing conditions under which OTC nighttime sleep-aid drug products are generally recognized as safe and effective (GRASE). This final OTC monograph was codified in 21 CFR part 338 and subsequently amended by final rules issued on April 11, 1994 (59 FR 16981 at 16983), and December 6, 2002 (67 FR 74555 at 72559).

Accordingly, this final order for OTC nighttime sleep-aid drug products incorporates the requirements of the final monograph for OTC nighttime sleep-aid drug products issued under part 330, as codified in part 338 as of March 27, 2020, with technical amendments, including formatting and harmonizing language.

III. Final Administrative Order

Over-the-Counter Monograph M010:
Nighttime Sleep-Aid Drug Products for Over-the-Counter Human Use

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SOURCE: 54 FR 6826, Feb. 14, 1989, unless otherwise noted.

Part A—General Provisions

§ M010.1 Scope

An over-the-counter nighttime (OTC) sleep-aid drug product 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.

§ M010.3 Definition

As used in this OTC monograph:

Nighttime sleep-aid. A drug that is useful for the relief of occasional sleeplessness by individuals who have difficulty falling asleep.

Part B—Active Ingredients

§ M010.10 Nighttime sleep-aid active ingredients

The active ingredient of the product consists of any of the following when used within the dosage limits established for each ingredient in § M010.50(d):

(a) Diphenhydramine hydrochloride.

(b) Diphenhydramine citrate.

Part C—Labeling

§ M010.50 Labeling of nighttime sleep-aid 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 a "nighttime sleep-aid."

(b) Indications. The labeling of the product states, under the heading "Uses," one or more of the phrases listed in § M010.50(b). Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in § M010.50(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) ("Helps you" or "Reduces time to") "fall asleep if you have difficulty falling asleep."

(2) "For relief of occasional sleeplessness."

(3) "Helps to reduce difficulty falling asleep."

(c) Warnings. The labeling of the product contains the following warnings under the heading "Warnings":

(1) "Do not give to children under 12 years of age."

(2) "If sleeplessness persists continuously for more than 2 weeks, consult your doctor. Insomnia may be a symptom of serious underlying medical illness."

(3) "Do not take this product, unless directed by a doctor, if you have a breathing problem such as emphysema or chronic bronchitis, or if you have glaucoma or difficulty in urination due to enlargement of the prostate gland."

(4) "Avoid alcoholic beverages while taking this product. Do not take this product if you are taking sedatives or tranquilizers, without first consulting your doctor."

(5) "Do not use [bullet][4] with any other product containing diphenhydramine, even one used on skin".

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

(1) For products containing diphenhydramine hydrochloride identified in § M010.10(a). Adults and children 12 years of age and over: Oral dosage is 50 milligrams at bedtime if needed, or as directed by a doctor.

(2) For products containing diphenhydramine citrate identified in § M010.10(b). Adults and children 12 years of age and over: Oral dosage is 76 milligrams at bedtime if needed, or as directed by a doctor.

(e) The word "physician" may be substituted for the word "doctor" in any of the labeling statements in § M010.50.

[54 FR 6826, Feb. 14, 1989, as amended at 59 FR 16983, Apr. 11, 1994; 67 FR 72559, Dec. 6, 2002]

[4] See 21 CFR 201.66(b)(4) for definition of bullet symbol.