

**U.S. Food and Drug Administration**

**Final Administrative Order (OTC000014)**

**Over-the-Counter Monograph M009:  
Antiemetic Drug Products for Over-the-Counter Human Use  
(Posted November 23, 2021)**

**I. Summary**

Over-the-Counter Monograph M009: Antiemetic 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)),<sup>1</sup> as well as other requirements,<sup>2</sup> 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.<sup>3</sup> 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

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<sup>1</sup> 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.

<sup>2</sup> Section 505G(a)(1)(A) of the FD&C Act.

<sup>3</sup> 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 April 30, 1987 (52 FR 15892), FDA issued a final OTC monograph under the procedure in part 330, establishing conditions under which OTC antiemetic drug products are generally recognized as safe and effective (GRASE). This final OTC monograph was codified in 21 CFR part 336 and subsequently amended by final rules issued on September 15, 1988 (53 FR 35809), April 11, 1994 (59 FR 16982), and December 6, 2002 (67 FR 72559).

Accordingly, this final order for OTC antiemetic drug products incorporates the requirements of the final monograph for OTC antiemetic drug products issued under part 330, as codified in part 336 as of March 27, 2020, with technical amendments including consolidating a professional use provision into its own part.

### **III. Final Administrative Order**

#### **Over-the-Counter Monograph M009: Antiemetic Drug Products for Over-the-Counter Human Use**

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SOURCE: 52 FR 15892, Apr. 30, 1987, unless otherwise noted.

## **Part A—General Provisions**

### **§ M009.1 Scope**

An over-the-counter (OTC) antiemetic drug 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 conditions in this OTC monograph and each of the general conditions established in 21 CFR 330.1.

### **§ M009.3 Definition**

As used in this OTC monograph:

Antiemetic. An agent that prevents or treats nausea and vomiting.

## **Part B—Active Ingredients**

### **§ M009.10 Antiemetic 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 § M009.50(d):

- (a) Cyclizine hydrochloride.
- (b) Dimenhydrinate.
- (c) Diphenhydramine hydrochloride.
- (d) Meclizine hydrochloride.

## **Part C—Labeling**

### **§ M009.50 Labeling of antiemetic 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 "antiemetic."

(b) Indications. The labeling of the product states the following under the heading "Uses," "For the prevention and treatment of the nausea, vomiting, or dizziness associated with motion sickness." Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in § M009.50(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)).

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

(1) For products containing any ingredient identified in § M009.10

(i) When labeled for use in adults and for those products that can be and are labeled for use in children under 12 years of age. "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."

(ii) For those products that can be and are labeled only for children under 12 years of age. "Do not give this product to children who have a breathing problem such as chronic bronchitis or who have glaucoma, without first consulting the child's doctor."

(2) For products containing cyclizine hydrochloride identified in § M009.10(a). "Do not give to children under 6 years of age unless directed by a doctor."

(3) For products containing dimenhydrinate identified in § M009.10(b). "Do not give to children under 2 years of age unless directed by a doctor."

(4) For products containing diphenhydramine hydrochloride identified in § M009.10(c). "Do not give to children under 6 years of age unless directed by a doctor."

(5) For products containing meclizine hydrochloride identified in § M009.10(d). "Do not give to children under 12 years of age unless directed by a doctor."

(6) For products containing cyclizine hydrochloride identified in § M009.10(a) or meclizine hydrochloride identified in § M009.10(d). "May cause drowsiness; alcohol, sedatives, and tranquilizers may increase the drowsiness effect. Avoid alcoholic beverages while taking this product. Do not take this product if you are taking sedatives or tranquilizers, without first consulting your doctor. Use caution when driving a motor vehicle or operating machinery."

(7) For products containing dimenhydrinate identified in § M009.10(b) or diphenhydramine hydrochloride identified in § M009.10(c). "May cause marked drowsiness; alcohol, sedatives, and tranquilizers may increase the drowsiness effect. Avoid alcoholic beverages while taking this product. Do not take this product if you are taking sedatives or tranquilizers, without first consulting your doctor. Use caution when driving a motor vehicle or operating machinery."

(8) For products containing diphenhydramine hydrochloride identified in § M009.10(c). "Do not use [bullet]<sup>4</sup> with any other product containing diphenhydramine, including one used on skin".

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

(1) For products containing cyclizine hydrochloride identified in § M009.10(a). Adults and children 12 years of age and over: Oral dosage is 50 milligrams every 4 to 6 hours, not to exceed 200 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: Oral dosage is 25 milligrams every 6 to 8 hours, not to exceed 75 milligrams in 24 hours, or as directed by a doctor.

(2) For products containing dimenhydrinate identified in § M009.10(b). Adults and children 12 years of age and over: Oral dosage is 50 to 100 milligrams every 4 to 6 hours, not to exceed 400 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: Oral dosage is 25 to 50 milligrams every 6 to 8 hours, not to exceed 150 milligrams in 24 hours, or as directed by a doctor. Children 2 to under 6 years of age: Oral dosage is 12.5 to 25 milligrams every 6 to 8 hours, not to exceed 75 milligrams in 24 hours, or as directed by a doctor.

(3) For products containing diphenhydramine hydrochloride identified in § M009.10(c). Adults and children 12 years of age and over: Oral dosage is 25 to 50 milligrams every 4 to 6 hours, not to exceed 300 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: Oral dosage is 12.5 to 25 milligrams every 4 to 6 hours, not to exceed 150 milligrams in 24 hours, or as directed by a doctor.

(4) For products containing meclizine hydrochloride identified in § M009.10(d). Adults and children 12 years of age and over: Oral dosage is 25 to 50 milligrams once daily, or as directed by a doctor.

(e) The word "physician" may be substituted for the word "doctor" in any of the labeling statements in § M009.50.

[52 FR 15892, Apr. 30, 1987; as amended at 53 FR 35809, Sept. 15, 1988; 59 FR 16982, Apr. 11, 1994; 67 FR 72559, Dec. 6, 2002]

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<sup>4</sup> See 21 CFR 201.66(b)(4) for definition of bullet symbol.

## **Part D—Professional Use**

### **§ M009.80 Professional labeling**

The labeling provided to health professionals (but not to the general public) may contain the following additional indications.

(a) For products containing cyclizine hydrochloride, dimenhydrinate, and diphenhydramine hydrochloride identified in §§ M009.10(a), (b), and (c). "For the treatment of vertigo of motion sickness."

(b) For products containing meclizine hydrochloride identified in § M009.10(d). "For the treatment of vertigo."