U.S. FOOD & DRUG ADMINISTRATION

U.S. Food and Drug Administration

Final Administrative Order (OTC000029)

Over-the-Counter Monograph M023: Poison Treatment Drug Products for Over-the-Counter Human Use (Posted October 14, 2022)

I. Summary

Over-the-Counter Monograph M023: Poison Treatment 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 January 15, 1985 (50 FR 2244), FDA published a proposed rule in the form of a tentative final monograph under the procedure in part 330, establishing conditions under which OTC poison treatment drug products are generally recognized as safe and effective (GRASE) (see also technical corrections on February 15, 1985 (50 FR 6359) and March 6, 1985 (50 FR 9040)).

Accordingly, this final order for OTC poison treatment products incorporates the requirements of the tentative final monograph for OTC poison treatment drug products issued under part 330 as proposed in the *Federal Register* on January 15, 1985 (50 FR 2244), with technical amendments.

III. Final Administrative Order

Over-the-Counter Monograph M023:

Poison Treatment Drug Products for Over-the-Counter Human Use

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SOURCE: 50 FR 2244, Jan. 15, 1985, unless otherwise noted.

Part A—General Provisions

§ M023.1 Scope

An over-the-counter (OTC) poison treatment 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.

§ M023.3 Definitions

As used in this OTC monograph:

(a) Adsorbent. An agent that causes another substance to adhere to its surface.

(b) Emesis. Vomiting.

(c) Emetic. An agent that causes vomiting (emesis).

§ M023.10 Active ingredients for poison treatment

The active ingredients of the product consist of any of the following when used within the dosage limits established for each ingredient:

(a) Charcoal, activated. The active ingredient is in a formulation such that the equivalent of one gram activated charcoal meets or exceeds the standards of adsorption for activated charcoal, United States Pharmacopeia (USP).

(b) Ipecac syrup. The active ingredient of the product is powdered ipecac. It is marketed as ipecac syrup, USP in the quantity of 1 fluid ounce (30 milliliters) only.

§ M023.14 Poison treatment kit

The kit is a single outer package labeled according to §§ M023.50 and M023.58 that consists of one 30 milliliter container of ipecac syrup identified in § M023.10(b) and a minimum of one dose 20 grams of activated charcoal identified in § M023.10(a).

§ M023.50 Principal display panel of all poison treatment drug products

In addition to the statements of identity required in §§ M023.52, M023.54, or M023.56, the principal display panel contains the following information:

(a) The following statements should appear in a conspicuously boxed area.

(1) "If possible call a Poison Control Center, emergency medical facility, or health professional for help before using this product."

(2) "If help cannot be reached quickly, follow the directions" (manufacturer to indicate location of directions, e.g., on the back of the bottle).

(3) "Read the warnings and directions as soon as you buy this product. Insert emergency phone number(s) in space provided on the label."

(b) A space must also be provided for writing in phone number(s) of the appropriate Poison Control Center, emergency medical facility, or health professional.

§ M023.52 Labeling of activated charcoal drug products

In addition to the labeling identified in § M023.50, the labeling of the product containing the ingredient identified in § M023.10(a) contains the following:

(a) Statement of identity. The labeling of the product includes the established name of the drug, if any, and identifies the product as a "poison adsorbent" "emergency poison adsorbent," or "first aid poison adsorbent."

(b) Indication. The labeling of the product contains a statement of the indications under the heading "Uses" that is limited to the phrase "For emergency use to adsorb swallowed poisons."

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

(1) "Do not give activated charcoal until after the patient has vomited unless directed by a health professional."

(2) "Do not use in persons who are not fully conscious."

(3) "Do not use this product, unless directed by a health professional, if turpentine, corrosives (such as alkalies (lye) and strong acids), or petroleum distillates (such as kerosene, gasoline, paint thinner, cleaning fluid, or furniture polish), have been ingested."

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

(1) Oral dosage: 20 to 30 grams of activated charcoal in a minimum of 8 ounces of liquid or as directed by a health professional.

(2) "Repeat dose immediately, if possible."

(3) "If previous attempts to contact a poison control center, emergency medical facility, or health professional were unsuccessful, continue trying."

(4) "Keep patient active and moving."

(5) "Save the container of poison."

§ M023.54 Labeling of ipecac syrup drug products

In addition to the labeling identified in § M023.50 the labeling of the product containing the ingredient identified in § M023.10(b) contains the following:

(a) Statement of identity. The labeling of the product includes the established name of the drug, if any, and identifies the product as an "emetic."

(b) Indications. The labeling of the product contains a statement of the indications under the heading "Uses" that is limited to the phrase "For emergency use to cause vomiting of swallowed poisons."

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

(1) "Do not use in persons who are not fully conscious."

(2) "Do not use this product, unless directed by a health professional, if turpentine, corrosives (such as alkalies (lye) and strong acids), or petroleum distillates (such as kerosene, gasoline, paint thinner, cleaning fluid, or furniture polish) have been ingested."

(3) "Do not administer milk with this product."

(4) "Drug Interaction Precaution: Activated charcoal will adsorb ipecac syrup. Do not give activated charcoal until after the patient has vomited, unless directed by a health professional."

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

(1) Adults and children 12 years of age and over: oral dosage is 2 tablespoonsful (30 milliliters or 1 bottle) followed by 1 to 2 glasses (8 to 16 ounces) of water or other clear liquid or as directed by a health professional.

(2) Children 1 to under 12 years of age: oral dosage is 1 tablespoonful (15 milliliters or 1/2 bottle) followed by 1 to 2 glasses (8 to 16 ounces) of water or other clear liquid or as directed by a health professional.

(3) Children 6 months to under 1 year of age: oral dosage is 1 teaspoonful (5 milliliters) followed by 1/2 to 1 glass (4 to 8 ounces) of water or other clear liquid or as directed by a health professional.

(4) Children under 6 months of age: Do not administer unless directed by a health professional."

(5) "If vomiting does not occur within 30 minutes, repeat the dose."

(6) "If previous attempts to contact a poison control center, emergency medical facility, or health professional were unsuccessful, continue trying."

(7) "Keep patient active and moving."

(8) "Save the container or poison."

§ M023.56 Labeling of poison treatment kits

The individual components of the kit must contain the labeling identified in §§ M023.52 and M023.54. The outer label of the kit must contain the information identified in § M023.50 and, in addition, the following:

(a) Statement of identity. The labeling of the product includes the established name of the drugs, if any, and identifies the product as a "Poison treatment kit," "Emergency poison treatment kit," or "Emergency first aid poison treatment kit."

(b) Directions. The labeling contains the following information under the heading "Directions": "When professional advice is not available, first give ipecac syrup to induce vomiting; after vomiting has occurred, give activated charcoal to help adsorb any remaining toxic substance."

§ M023.58 Other allowable statements for poison treatment drug products

The following additional statements may be included in the labeling of poison treatment drug products, but should not be included in conjunction with the required labeling identified in §§ M023.50, M023.52, M023.54, and M023.56:

(a) "For the treatment of poisoning."

(b) "Emergency first aid treatment for poisoning."

(c) "Emergency treatment for poisoning."

(d) "Emergency treatment for accidental poisoning."

(e) "For the treatment of accidental poisoning."

(f) "Emergency first aid treatment for accidental poisoning.

(g) "Emergency poison treatment."

(h) "First aid poison treatment."

§ M023.60 Nonapplicability of 21 CFR 330.1(g) to poison treatment drug products

The second portion of the warning required by 21 CFR 330.1(g) concerning accidental overdose is not required on poison treatment drug products.