

U.S. Food and Drug Administration

Final Administrative Order (OTC000019)

Over-the-Counter Monograph M025: Cholecystokinetic Drug Products for Over-the-Counter Human Use (Posted December 16, 2021)

I. Summary

Over-the-Counter Monograph M025: Cholecystokinetic 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 June 10, 1983 (48 FR 27004 at 27005), FDA issued a final OTC monograph under the procedure in part 330, establishing conditions under which OTC cholecystokinetic drug products are generally recognized as safe and effective (GRASE). This final OTC monograph was codified in 21 CFR part 357, subpart C, and subsequently amended by final rules issued on May 1, 1986 (51 FR 16258 at 16266-67), March 13, 1987 (52 FR 7830), and February 28, 1989 (54 FR 8320 at 8321).

Accordingly, this final order for OTC cholecystokinetic drug products incorporates the requirements of the final monograph for OTC cholecystokinetic drug products issued under part 330, as codified in part 357, subpart C 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 M025: Cholecystokinetic Drug Products for Over-the-Counter Human Use

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SOURCE: 48 FR 27005, June 10, 1983, unless otherwise noted.

Part A—General Provisions

§ M025.1 Scope

An over-the-counter (OTC) cholecystokinetic 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 in addition to each of the general conditions established in 21 CFR 330.1.

[48 FR 27005, June 10, 1983]

§ M025.3 Definition

As used in this OTC monograph:

Cholecystokinetic drug product. A drug product that causes contraction of the gallbladder and is used during the course of diagnostic gallbladder studies (cholecystography).

[48 FR 27005, June 10, 1983]

Part B—Active Ingredients

§ M025.10 Cholecystokinetic active ingredients

The active ingredient of the product consists of any of the following when used within the specified concentration and dosage form established for each ingredient:

- (a) 50-percent aqueous emulsion of corn oil.

(b) Hydrogenated soybean oil in a suitable, water-dispersible powder. The hydrogenated soybean oil is food-grade, partially hydrogenated with a melting point of 41 to 43.5 °C, an iodine value of 65 to 69, and a fatty acid composition as follows:

Fatty acid	Percent composition
Myristic acid	0.1
Palmitic acid	10.0
Palmitoleic acid	0.1
Stearic acid	13.5
Oleic acid	72.0
Linoleic acid	3.8
Linolenic acid	0.1
Arachidic acid	0.5
Behenic acid	0.2

[54 FR 8321, Feb. 28, 1989]

Part C—Labeling

§ M025.50 Labeling of cholecystokinetic 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 “gallbladder diagnostic agent.”

(b) Indications. The labeling of the product states, under the heading “Uses,” the following: “For the contraction of the gallbladder during diagnostic gallbladder studies.” Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in § M025.50(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) Directions. The labeling of the product contains the following statements under the heading “Directions”:

(1) “Take only when instructed by a doctor:”

(2) For products containing 50-percent aqueous emulsion of corn oil.

(i) “Shake well before using.”

(ii) Oral dosage is 60 milliliters 20 minutes before diagnostic gallbladder x-ray or as directed by a doctor.

(3) For products containing hydrogenated soybean oil. Oral dosage is 12.4 grams in a suitable, water-dispersible powder in 2 to 3 ounces of water. Stir briskly to prepare a suspension before using. Drink 20 minutes before diagnostic gallbladder x-ray or as directed by a doctor.

(e) The word “physician” may be substituted for the word “doctor” in any of the labeling statements in § M025.50.

[48 FR 27005, June 10, 1983, as amended at 51 FR 16267, May 1, 1986; 52 FR 7830, Mar. 13, 1987; 54 FR 8321, Feb. 28, 1989]

Part D—Professional Use

§ M025.80 Professional labeling

The labeling provided to health professionals (but not to the general public) may contain the following information for ingredients identified in § M025.10: Indication. “For visualization of biliary ducts during cholecystography.”

[54 FR 8321, Feb. 28, 1989]