



U.S. Food and Drug Administration

Final Administrative Order (OTC000003)

Over-the-Counter Monograph M014: Topical Otic Drug Products for Over-the-Counter Human Use (Posted September 20, 2021)

I. Summary

Over-the-Counter Monograph M014: Topical Otic 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 August 8, 1986 (51 FR 28656 at 28660), FDA issued a final OTC monograph under the procedure in part 330, establishing conditions under which OTC topical otic drug products are generally recognized as safe and effective (GRASE). This final OTC monograph was codified in 21 CFR part 344 and subsequently amended by final rules issued on March 13, 1987 (52 FR 7830) and August 10, 2000 (65 FR 48902 at 48905).

Accordingly, this final order for OTC topical otic drug products incorporates the requirements of the final monograph for OTC topical otic drug products issued under part 330, as codified in part 344 as of March 27, 2020, with technical amendments, including formatting and harmonizing language.

III. Final Administrative Order

Over-the-Counter Monograph M014: Topical Otic Drug Products for Over-the-Counter Human Use

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SOURCE: 51 FR 28656 at 28660, Aug. 8, 1986, unless otherwise noted.

Part A—General Provisions

§ M014.1 Scope

An over-the-counter (OTC) topical otic drug product in a form suitable for topical 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.

§ M014.3 Definitions

As used in this OTC monograph:

(a) Anhydrous glycerin. An ingredient that may be prepared by heating glycerin USP at 150 °C for 2 hours to drive off the moisture content.

(b) Earwax removal aid. A drug used in the external ear canal that aids in the removal of excessive earwax.

(c) Water-clogged ears. The retention of water in the external ear canal, thereby causing discomfort and a sensation of fullness or hearing impairment.

(d) Ear drying aid. A drug used in the external ear canal to help dry water-clogged ears.

[51 FR 28656 at 28660, Aug. 8, 1986, as amended by 65 FR 48902 at 48905, Aug. 10, 2000]

Part B—Active Ingredients

§ M014.10 Earwax removal aid active ingredient

The active ingredient of the product consists of carbamide peroxide 6.5 percent formulated in an anhydrous glycerin vehicle.

[51 FR 28656 at 28660, Aug. 8, 1986, as amended by 65 FR 48902 at 48905, Aug. 10, 2000]

§ M014.12 Ear drying aid active ingredient

The active ingredient of the product consists of isopropyl alcohol 95 percent in an anhydrous glycerin 5 percent base.

[65 FR 48902 at 48905, Aug. 10, 2000]

Part C—Labeling

§ M014.50 Labeling of earwax removal 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 an “earwax removal aid.”

(b) Indication. The labeling of the product states, under the heading “Use,” the following: “For occasional use as an aid to” (which may be followed by: “soften, loosen, and”) “remove excessive earwax.” Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in § M014.50(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) “Do not use if you have ear drainage or discharge, ear pain, irritation, or rash in the ear or are dizzy; consult a doctor.”
- (2) “Do not use if you have an injury or perforation (hole) of the ear drum or after ear surgery unless directed by a doctor.”
- (3) “Do not use for more than 4 days; if excessive earwax remains after use of this product, consult a doctor.”
- (4) “Avoid contact with the eyes.”

(d) Directions. The labeling of the product contains the following statement under the heading “Directions”: FOR USE IN THE EAR ONLY. Adults and children over 12 years of age: tilt head sideways and place 5 to 10 drops into ear. Tip of applicator should not enter ear canal. Keep drops in ear for several minutes by keeping head tilted or placing cotton in the ear. Use twice daily for up to 4 days if needed, or as directed by a doctor. Any wax remaining after treatment may be removed by gently flushing the ear with warm water, using a soft rubber bulb ear syringe. Children under 12 years of age: consult a doctor.

[51 FR 28656 at 28660, Aug. 8, 1986; 52 FR 7830, Mar. 13, 1987; 65 FR 48902 at 48905, Aug. 10, 2000]

§ M014.52 Labeling of ear drying 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 an “ear drying aid.”

(b) Indications. The labeling of the product states, under the heading “Use,” the following: “dries water in the ears” (optional, which may be followed by: “and relieves water-clogged ears”) (which may be followed by any or all of the following: “after: [bullet]⁴ swimming [bullet] showering [bullet] bathing [bullet] washing the hair”). Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in § M014.52(b), may also be used, as provided in 21 CFR 330.1(c)(2), subject to the provisions of section 502 of the FD&C Act relating to misbranding and the prohibition in section 301(d) of the FD&C Act 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.

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

(1) “Flammable [in bold type]: Keep away from fire or flame.”

(2) “Do not use [in bold type] in the eyes.”

(3) “Ask a doctor before use if you have [in bold type] [bullet] ear drainage or discharge [bullet] pain, irritation, or rash in the ear [bullet] had ear surgery [bullet] dizziness.”

(4) “Stop use and ask a doctor if [in bold type] irritation (too much burning) or pain occurs.”

(d) Directions. The labeling of the product contains the following statement under the heading “Directions”: [optional, bullet] “apply 4 to 5 drops in each affected ear.”

[65 FR 48902 at 48905, Aug. 10, 2000]

⁴ See 21 CFR 201.66(b)(4).