U.S. Food and Drug Administration

Final Administrative Order (OTC000004)

Over-the-Counter Monograph M030: Corn and Callus Remover Drug Products for Over-the-Counter Human Use (Posted September 20, 2021)

I. Summary

Over-the-Counter Monograph M030: Corn and Callus Remover 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 14, 1990 (55 FR 33258 at 33261), FDA issued a final OTC monograph under the procedure in part 330, establishing conditions under which OTC corn and callus remover drug products are generally recognized as safe and effective (GRASE). This final OTC monograph was codified in 21 CFR part 358, subpart F and subsequently amended by a final rule issued on September 28, 1992 (57 FR 44494 at 44495).

Accordingly, this final order for OTC corn and callus remover drug products incorporates the requirements of the final monograph for OTC corn and callus remover drug products issued under part 330, as codified in part 358, subpart F as of March 27, 2020, with technical amendments, including formatting and harmonizing language.

III. Final Administrative Order

Over-the-Counter Monograph M030:
Corn and Callus Remover Drug Products for Over-the-Counter Human Use

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SOURCE: 55 FR 33261, Aug. 14, 1990, unless otherwise noted.

Part A—General Provisions

§ M030.1 Scope

An over-the-counter (OTC) corn and callus remover drug product in a form suitable for topical application 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.

§ M030.3 Definitions

As used in this OTC monograph:

(a) Corn and callus remover drug product. A topical agent used for the removal of corns and calluses.

(b) Collodion-like vehicle. A solution containing pyroxylin (nitrocellulose) in an appropriate nonaqueous solvent that leaves a transparent cohesive film when applied to the skin in a thin layer.

(c) Plaster vehicle. A fabric, plastic, or other suitable backing material in which medication is usually incorporated for topical application to the skin.

Part B—Active Ingredients

§ M030.10 Corn and callus remover active ingredients

The product consists of any of the following active ingredients within the specified concentrations and in the dosage form established for each ingredient.

(a) Salicylic acid 12 to 40 percent in a plaster vehicle.

(b) Salicylic acid 12 to 17.6 percent in a collodion-like vehicle.

Part C—Labeling

§ M030.50 Labeling of corn and callus remover 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 “corn and callus remover.”

(b) Indications. The labeling of the product states, under the heading "Uses," the phrase listed in § M030.50(b)(1) and may contain the additional phrase listed in §M030.50(b)(2). Other truthful and nonmisleading statements, describing only the indications for use that have been established in § M030.50(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) "For the removal of corns and calluses."

(2) In addition to the information identified in § M030.50(b)(1), the labeling of the product may contain the following statement: "Relieves pain by removing corns and calluses."

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

(1) For products containing any ingredient identified in § M030.10.

(i) "For external use only."

(ii) "Do not use this product on irritated skin, on any area that is infected or reddened, if you are a diabetic, or if you have poor blood circulation."

(iii) "If discomfort persists, see your doctor or podiatrist."

(2) For any product formulated in a flammable vehicle.

(i) The labeling should contain an appropriate flammability signal word, e.g., "extremely flammable," "flammable," "combustible," consistent with 16 CFR 1500.3(b)(10).

(ii) "Keep away from fire or flame."

(3) For any product formulated in a volatile vehicle. "Cap bottle tightly and store at room temperature away from heat."

(4) For any product formulated in a collodion-like vehicle.

(i) "If product gets into the eye, flush with water for 15 minutes."

(ii) "Avoid inhaling vapors."

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

(1) For products containing salicylic acid identified in § M030.10(a). “Wash affected area and dry thoroughly.” (If appropriate: “Cut plaster to fit corn/callus.”) “Apply medicated plaster. After 48 hours remove the medicated plaster. Repeat this procedure every 48 hours as needed for up to 14 days (until corn/callus is removed).” (Optional: “May soak corn/callus in warm water for 5 minutes to assist in removal.”)

(2) For products containing salicylic acid identified in § M030.10(b). “Wash affected area and dry thoroughly. Apply” (select one of the following, as appropriate: “one drop” or “small amount”) “at a time with” (select one of the following, as appropriate: “applicator” or “brush”) “to sufficiently cover each corn/callus. Let dry. Repeat this procedure once or twice daily as needed for up to 14 days (until corn/callus is removed).” (Optional: “May soak corn/callus in warm water for 5 minutes to assist in removal.”)

(e) The word “physician” may be substituted for the word “doctor” in any of the labeling statements in § M030.50.

[55 FR 33261, Aug. 14, 1990, as amended at 57 FR 44494, Sept. 28, 1992]