U.S. Food and Drug Administration

Final Administrative Order (OTC000021)

Over-the-Counter Monograph M032: Drug Products for the Control of Dandruff, Seborrheic Dermatitis, and Psoriasis for Over-the-Counter Human Use (Posted December 16, 2021)

I. Summary

Over-the-Counter Monograph M032: Drug Products for the Control of Dandruff, Seborrheic Dermatitis, and Psoriasis 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.

[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.

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 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 December 4, 1991 (56 FR 63568), FDA issued a final OTC monograph under the procedure in part 330, establishing conditions under which OTC drug products for the control of dandruff, seborrheic dermatitis, and psoriasis are generally recognized as safe and effective (GRASE). This final OTC monograph was codified in 21 CFR part 358, subpart H and subsequently amended by final rules issued on January 28, 1994 (59 FR 4001) and March 6, 2007 (72 FR 9852),

Accordingly, this final order for OTC drug products for the control of dandruff, seborrheic dermatitis, and psoriasis incorporates the requirements of the final monograph for OTC drug products for the control of dandruff, seborrheic dermatitis, and psoriasis issued under part 330, as codified in part 358, subpart H as of March 27, 2020, with technical amendments.

III. Final Administrative Order

Over-the-Counter Monograph M032:
Drug Products for the Control of Dandruff, Seborrheic Dermatitis, and Psoriasis for Over-the-Counter Human Use

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SOURCE: 56 FR 63568, Dec 4, 1991, unless otherwise noted.

Part A—General Provisions

§ M032.1 Scope

An over-the-counter (OTC) dandruff, seborrheic dermatitis, or psoriasis 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 general condition established in 21 CFR 330.1.

§ M032.3 Definitions

As used in this OTC monograph:

(a) Coal tar. The tar used for medicinal purposes that is obtained as a byproduct during the destructive distillation of bituminous coal at temperatures in the range of 900 °C to 1,100 °C. It may be further processed using either extraction with alcohol and suitable dispersing agents and maceration times or fractional distillation with or without the use of suitable organic solvents.

(b) Dandruff. A condition involving an increased rate of shedding of dead epidermal cells of the scalp.

(c) Psoriasis. A condition of the scalp or body characterized by irritation, itching, redness, and extreme excess shedding of dead epidermal cells.

(d) Seborrheic dermatitis. A condition of the scalp or body characterized by irritation, itching, redness, and excess shedding of dead epidermal cells.

(e) Selenium sulfide, micronized. Selenium sulfide that has been finely ground and that has a median particle size of approximately 5 micrometers (µm), with not more than 0.1 percent of the particles greater than 15 µm and not more than 0.1 percent of the particles less than 0.5 µm.

[56 FR 63568, Dec. 4, 1991, as amended at 59 FR 4001, Jan. 28, 1994]

Part B—Active Ingredients

§ M032.10 Active ingredients for the control of dandruff, seborrheic dermatitis, or psoriasis

The active ingredient of the product consists of any of the following within the specified concentration established for each ingredient:

(a) Active ingredients for the control of dandruff.

(1) Coal tar, 0.5 to 5 percent. When a coal tar solution, derivative, or fraction is used as the source of the coal tar, the labeling shall specify the identity and concentration of the coal tar source used and the concentration of the coal tar present in the final product.

(2) Pyrithione zinc, 0.3 to 2 percent when formulated to be applied and then washed off after brief exposure.

(3) Pyrithione zinc, 0.1 to 0.25 percent when formulated to be applied and left on the skin or scalp.

(4) Salicylic acid, 1.8 to 3 percent.

(5) Selenium sulfide, 1 percent.

(6) Selenium sulfide, micronized, 0.6 percent.

(7) Sulfur, 2 to 5 percent.

(b) Active ingredients for the control of seborrheic dermatitis.

(1) Coal tar, 0.5 to 5 percent. When a coal tar solution, derivative, or fraction is used as the source of the coal tar, the labeling shall specify the identity and concentration of the coal tar source used and the concentration of the coal tar present in the final product.

(2) Pyrithione zinc, 0.95 to 2 percent when formulated to be applied and then washed off after brief exposure.

(3) Pyrithione zinc, 0.1 to 0.25 percent when formulated to be applied and left on the skin or scalp.

(4) Salicylic acid, 1.8 to 3 percent.

(5) Selenium sulfide, 1 percent.

(c) Active ingredients for the control of psoriasis.

(1) Coal tar, 0.5 to 5 percent. When a coal tar solution, derivative, or fraction is used as the source of the coal tar, the labeling shall specify the identity and concentration of the coal tar source used and the concentration of the coal tar present in the final product.

(2) Salicylic acid, 1.8 to 3 percent.

[56 FR 63568, Dec. 4, 1991, as amended at 59 FR 4001, Jan. 28, 1994]

§ M032.20 Permitted combinations of active ingredients

(a) Combination of active ingredients for the control of dandruff. Salicylic acid identified in § M032.10(a)(4) may be combined with sulfur identified in § M032.10(a)(7) provided each ingredient is present within the established concentration and the product is labeled according to § M032.50.

(b) Combination of control of dandruff and external analgesic active ingredients. Coal tar identified in § M032.10(a)(1) may be used at a concentration of 1.8 percent coal tar solution, on a weight to volume basis, in combination with menthol, 1.5 percent, in a shampoo formulation provided the product is labeled according to § M032.60.

[72 FR 9852, Mar. 6, 2007]

Part C—Labeling

§ M032.50 Labeling of drug products for the control of dandruff, seborrheic dermatitis, or psoriasis

(a) Statement of identity. The labeling of the product contains the established name of the drug, if any, and identifies the product with one or more of the following, as appropriate:

(1) “Dandruff (insert product form)” or “antidandruff (insert product form)”.

(2) “Seborrheic dermatitis (insert product form)”.

(3) “Psoriasis (insert product form)”.

(b) Indications. The labeling of the product states, under the heading "Uses," the phrase listed in § M032.50(b)(1) and may contain any of the terms listed in §§ M032.50(b)(2) or (b)(3). Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in § M032.50(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 relief of" or "Controls") "the symptoms of" (select one or more of the following, as appropriate: "dandruff," "seborrheic dermatitis," and/or "psoriasis.")

(2) The following terms or phrases may be used in place of or in addition to the words "For the relief of" or "Controls" in the indications in § M032.50(b)(1): "fights," "reduces," "helps eliminate," "helps stop," "controls recurrence of," "fights recurrence of," "helps prevent recurrence of," "reduces recurrence of," "helps eliminate recurrence of," "helps stop recurrence of."

(3) The following terms may be used in place of the words "the symptoms of" in the indications in § M032.50(b)(1): ("skin" and/or "scalp," as appropriate) (select one or more of the following: "itching," "irritation," "redness," "flaking," "scaling,") "associated with."

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

(1) For products containing any ingredient identified in § M032.10.

(i) "For external use only."

(ii) "Avoid contact with the eyes. If contact occurs, rinse eyes thoroughly with water."

(iii) "If condition worsens or does not improve after regular use of this product as directed, consult a doctor."

(2) For any product containing coal tar identified in §§ M032.10(a), (b), or (c).

(i) "Use caution in exposing skin to sunlight after applying this product. It may increase your tendency to sunburn for up to 24 hours after application."

(ii) "Do not use for prolonged periods without consulting a doctor."

(3) For products containing coal tar when formulated to be applied and left on the skin (e.g., creams, ointments, lotions). “Do not use this product in or around the rectum or in the genital area or groin except on the advice of a doctor.”

(4) For products containing coal tar identified in § M032.10(c) for the control of psoriasis. “Do not use this product with other forms of psoriasis therapy such as ultraviolet radiation or prescription drugs unless directed to do so by a doctor.”

(5) For products containing any ingredient identified in §§ M032.10(b) or (c) for the control of seborrheic dermatitis or psoriasis. “If condition covers a large area of the body, consult your doctor before using this product.”

(d) Directions. The labeling of the product contains the following information under the heading “Directions.” More detailed directions applicable to a particular product formulation may also be included.

(1) For products containing active ingredients for the control of dandruff, seborrheic dermatitis, or psoriasis when formulated to be applied and then washed off after brief (a few minutes) exposure (e.g., shampoos, preshampoo rinses, postshampoo rinses). “For best results use at least twice a week or as directed by a doctor.”

(2) For products containing active ingredients for the control of dandruff, seborrheic dermatitis, or psoriasis when formulated so as to be applied and left on the skin or scalp (e.g., creams, ointments, lotions, hairgrooms). “Apply to affected areas one to four times daily or as directed by a doctor.”

(3) For products containing active ingredients for the control of seborrheic dermatitis or psoriasis of the skin when formulated as soaps. “Use on affected areas in place of your regular soap.”

(e) The word “physician” may be substituted for the word “doctor” in any of the labeling statements in § M032.50.

§ M032.60 Labeling of permitted combinations of active ingredients for the control of dandruff

The statement of identity, indications, warnings, and directions for use, respectively, applicable to each ingredient in the product may be combined to eliminate duplicative words or phrases so that the resulting information is clear and understandable.

(a) Statement of identity. For a combination drug product that has an established name, the labeling of the product states the established name of the combination drug product, followed by the statement of identity for each ingredient in the combination, as established in the statement of identity sections of the applicable OTC monographs.

(1) Combinations of control of dandruff and external analgesic active ingredients in § M032.20(b). The label states “dandruff/anti-itch shampoo” or “antidandruff/anti-itch shampoo”.

(b) Indications. The labeling of the product states, under the heading “Uses,” one or more of the phrases listed in § M032.60(b) as appropriate. Other truthful and nonmisleading statements, describing only the uses that have been established and listed in § M032.60(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.

(1) Combinations of control of dandruff and external analgesic active ingredients in § M032.20(b). The labeling states “[bullet] [select one of the following: ‘for relief of' or ‘controls'] the symptoms of dandruff [bullet] [select one of the following: ‘additional' or ‘extra'] relief of itching due to dandruff”.

(2) The following terms or phrases may be used in place of or in addition to the words “for the relief of” or “controls” in the indications in § M032.60(b)(1): “fights,” “reduces,” “helps eliminate,” “helps stop,” “controls recurrence of,” “fights recurrence of,” “helps prevent recurrence of,” “reduces recurrence of,” “helps eliminate recurrence of,” “helps stop recurrence of.”

(3) The following terms may be used in place of the words “the symptoms of” in the indication in § M032.60(b)(1): “scalp” (select one or more of the following: “itching,” “irritation,” “redness,” “flaking,” “scaling”) “associated with”.

(c) Warnings. The labeling of the product states, under the heading “Warnings,” the warning(s) listed in §§ M032.50(c)(1) and (c)(2).

(d) Directions. The labeling of the product states, under the heading “Directions,” directions that conform to the directions established for each ingredient in the directions sections of the applicable OTC monographs, unless otherwise stated in § M032.60(d). When the time intervals or age limitations for administration of the individual ingredients differ, the directions for the combination product may not contain any dosage that exceeds those established for any individual ingredient in the applicable OTC monograph(s), and may not provide for use by any age group lower than the highest minimum age limit established for any individual ingredient.

(1) Combinations of control of dandruff and external analgesic active ingredients in § M032.20(b). The labeling states “[bullet] wet hair [bullet] apply shampoo and work into a lather [bullet] rinse thoroughly [bullet] for best results, use at least twice a week or as directed by a doctor”.

[72 FR 9852, Mar. 6, 2007]