

U.S. Food and Drug Administration

Final Administrative Order (OTC000012)

**Over-the-Counter Monograph M031:
Pediculicide Drug Products for Over-the-Counter Human Use
(Posted October 1, 2021)**

I. Summary

Over-the-Counter Monograph M031: Pediculicide 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 December 14, 1993 (58 FR 65452 at 65455), FDA issued a final OTC monograph under the procedure in part 330, establishing conditions under which OTC pediculicide drug products are generally recognized as safe and effective (GRASE). This final OTC monograph was codified in 21 CFR part 358, subpart G and subsequently amended by final rules issued on August 13, 1998 (63 FR 43302 at 43303) and December 31, 2003 (68 FR 75414 at 75417).

Accordingly, this final order for OTC pediculicide drug products incorporates the requirements of the final monograph for OTC pediculicide drug products issued under part 330, as codified in part 358, subpart G as of March 27, 2020, with technical amendments.

III. Final Administrative Order

Over-the-Counter Monograph M031: Pediculicide Drug Products for Over-the-Counter Human Use

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SOURCE: 58 FR 65455, Dec. 14, 1993, unless otherwise noted.

Part A—General Provisions

§ M031.1 Scope

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

§ M031.3 Definition

As used in this OTC monograph:

Pediculicide drug product. A drug product for the treatment of head, pubic (crab), and body lice.

Part B—Active Ingredients

§ M031.10 Pediculicide active ingredients

The active ingredients of the product consist of the combination of pyrethrum extract (providing a concentration of pyrethrins of 0.17 to 0.33 percent) with piperonyl butoxide (2 to 4 percent) in a nonaerosol dosage formulation.

[63 FR 43303, Aug. 13, 1998]

Part C—Labeling

§ M031.50 Labeling of pediculicide 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 “lice treatment.”

(b) Indications. The labeling of the product states, under the heading “Uses,” the following: “treats head, pubic (crab), and body lice.” Other truthful and nonmisleading statements, describing only the uses that have been established and listed in § M031.50(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) “For external use only” in accord with 21 CFR 201.66(c)(5)(i).

(2) “Do not use [bullet]⁴ near eyes [bullet] inside nose, mouth, or vagina [bullet] on lice in eyebrows or eyelashes. See a doctor if lice are present in these areas.”

(3) “Ask a doctor before use if you are [bullet] allergic to ragweed. May cause breathing difficulty or an asthmatic attack.”

(4) “When using this product [bullet] keep eyes tightly closed and protect eyes with a washcloth or towel [bullet] if product gets in eyes, flush with water right away [bullet] scalp itching or redness may occur”.

(5) “Stop use and ask a doctor if [bullet] breathing difficulty occurs [bullet] eye irritation occurs [bullet] skin or scalp irritation continues or infection occurs”.

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

(1) The labeling states “[bullet] Important: Read warnings before use” [statement shall appear first and in bold type].

(2) The labeling states “adults and children 2 years and over:” [in bold type].

(3) For head lice treatment products “Inspect [in bold type] [bullet] check each household member with a magnifying glass in bright light for lice/nits (eggs) [bullet] look for tiny nits near scalp, beginning at back of neck and behind ears [bullet] examine small sections of hair at a time [bullet] unlike dandruff which moves when touched, nits stick to the hair [bullet] if either lice or nits are found, treat with this product”.

(4) Select one of the following:

(i) For shampoo products “Treat [in bold type] [bullet] apply thoroughly to (optional, may add “dry”) hair or other affected area. For head lice, first apply behind ears and to back of neck. [bullet] allow product to remain for 10 minutes, but no longer [bullet] use warm water to form a lather, shampoo, then thoroughly rinse [bullet] for head lice, towel dry hair and comb out tangles”.

(ii) For nonshampoo products “Treat [in bold type] [bullet] apply thoroughly to (optional, may add “dry”) hair or other affected area. For head lice, first apply behind ears and to back of neck. [bullet] allow product to remain for 10 minutes, but no longer [bullet] wash area thoroughly with warm water and soap or shampoo [bullet] for head lice, towel dry hair and comb out tangles”.

⁴ See 21 CFR 201.66(b)(4) for definition of bullet symbol.

(5) “Remove lice and their eggs (nits) [in bold type] [bullet] use a fine-tooth or special lice/nit comb. Remove any remaining nits by hand (using a throw-away glove). [bullet] hair should remain slightly damp while removing nits [bullet] if hair dries during combing, dampen slightly with water [bullet] for head lice, part hair into sections. Do one section at a time starting on top of head. Longer hair may take 1 to 2 hours. [bullet] lift a 1- to 2-inch wide strand of hair. Place comb as close to scalp as possible and comb with a firm, even motion away from scalp. [bullet] pin back each strand of hair after combing [bullet] clean comb often. Wipe nits away with tissue and discard in a plastic bag. Seal bag and discard to prevent lice from coming back. [bullet] after combing, thoroughly recheck for lice/nits. Repeat combing if necessary. [bullet] check daily for any lice/nits that you missed”.

(6) The labeling states “[bullet] a second treatment must be done in 7 to 10 days to kill any newly hatched lice”.

(7) The labeling states “[bullet] if infestation continues, see a doctor for other treatments”.

(8) The labeling states “children under 2 years:” [in bold type] “ask a doctor”.

(e) Other information. The labeling of the product contains the following statements, as appropriate, under the heading “Other information.” This information may appear in a package insert. If a package insert is used, the “Other information” section on the outer carton or container label shall include a statement referring to the package insert for additional information.

(1) “Head lice [highlighted in bold type] [bullet] lay small white eggs (nits) on hair shaft close to scalp [bullet] nits are most easily found on back of neck or behind ears [bullet] disinfect hats, hair ribbons, scarves, coats, towels, and bed linens by machine washing in hot water (above 54 °C (130 °F)), then using hottest dryer cycle for at least 20 minutes [bullet] items that cannot be washed (bedspreads, blankets, pillows, stuffed toys, etc.) should be dry-cleaned or sealed in a plastic bag for 4 weeks, then removed outdoors and shaken out very hard before using again [bullet] items that cannot be washed, dry-cleaned, or stored may be sprayed with a product designed for this purpose [bullet] soak all combs and brushes in hot water (above 54 °C (130 °F)) for at least 10 minutes [bullet] vacuum all carpets, mattresses, upholstered furniture, and car seats that may have been used by affected people”.

(2) “Pubic (crab) lice [highlighted in bold type] [bullet] may be transmitted by sexual contact. Sexual partners should be treated simultaneously to avoid reinfestation [bullet] lice are very small and look like brown or grey dots on skin [bullet] usually cause intense itching and lay small white eggs (nits) on the hair shaft generally close to the skin surface [bullet] may be present on the short hairs of groin, thighs, trunk, and underarms, and occasionally on the beard and mustache [bullet] disinfect underwear by machine washing in hot water (above 54 °C (130 °F)), then using hottest dryer cycle for at least 20 minutes”.

(3) “**Body lice** [bullet] body lice and their eggs (nits) are generally found in the seams of clothing particularly in waistline and armpit area [bullet] body lice feed on skin then return to clothing to lay their eggs [bullet] disinfect clothing by machine washing in hot water (above 54 °C (130 °F)), then using hottest dryer cycle for at least 20 minutes [bullet] do not seal clothing in a plastic bag because nits can remain dormant for up to 30 days”.

[68 FR 75417, Dec. 31, 2003]