U.S. Food and Drug Administration

Final Administrative Order (OTC000005)

Over-the-Counter Monograph M016: Skin Protectant Drug Products for Over-the-Counter Human Use (Posted September 24, 2021)

I. Summary

Over-the-Counter Monograph M016: Skin Protectant 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 October 21, 1993 (58 FR 54458 at 54462), FDA issued a final OTC monograph under the procedure in part 330, establishing conditions under which OTC skin protectant drug products are generally recognized as safe and effective (GRASE). This final OTC monograph was codified in part 347 (21 CFR part 347) and subsequently amended by final rules issued on June 4, 2003 (68 FR 33362 at 33376), June 13, 2003 (68 FR 35290 at 35293), December 9, 2003 (68 FR 68509 at 68511), January 22, 2004 (69 FR 3005), February 1, 2008 (73 FR 6014 at 6017), and March 6, 2009 (74 FR 9759 at 9765).

In the *Federal Register* of January 31, 1990 (55 FR 3362), FDA proposed to amend the tentative final monograph for OTC skin protectant drug products to establish the conditions under which OTC skin protectant drug products for the treatment of fever blisters and cold sores are GRASE. In the *Federal Register* of June 20, 1990 (55 FR 25204), FDA published a proposed rule to amend the tentative final monograph for OTC skin protectant drug products to establish conditions under which OTC skin protectant drug products for the treatment or prevention of diaper rash are GRASE.

Accordingly, this final order for OTC skin protectant drug products incorporates the requirements of the final monograph for OTC skin protectant drug products issued under part 330, as codified in part 347 as of March 27, 2020, and the proposed rules issued in the *Federal Register* on January 31, 1990 (55 FR 3362), and June 20, 1990 (55 FR 25204), with technical amendments.

III. Final Administrative Order

Over-the-Counter (OTC) Monograph

M016: Skin Protectant Drug Products for Over-the-Counter Human Use

Part A—General Provisions

Sec.
M016.1 Scope
M016.3 Definitions

Part B—Active Ingredients

M016.10 Skin protectant active ingredients
M016.12 Astringent active ingredients
M016.20 Permitted combinations of active ingredients

Part C—Labeling

M016.50 Labeling of skin protectant drug products
M016.52 Labeling of astringent drug products
M016.60 Labeling of permitted combinations of active ingredients

SOURCE: 58 FR 54462, Oct. 21, 1993, unless otherwise noted.

Part A—General Provisions

§ M016.1 Scope

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

§ M016.3 Definitions

As used in this OTC monograph:

(a) Astringent drug product. A drug product applied to the skin or mucous membranes for a local and limited protein coagulant effect.

(b) Lip protectant drug product. A drug product that temporarily prevents dryness and helps relieve chapping of the exposed surfaces of the lips; traditionally called "lip balm."

(c) Poison ivy, oak, sumac dermatitis. An allergic contact dermatitis due to exposure to plants of the genus Rhus (poison ivy, poison oak, poison sumac), which contain urushiol, a potent skin-sensitizer.

(d) Skin protectant drug product. A drug product that temporarily protects injured or exposed skin or mucous membrane surfaces from harmful or annoying stimuli, and may help provide relief to such surfaces.

(e) Diaper rash or diaper dermatitis. An inflammatory skin condition in the diaper area (perineum, buttocks, lower abdomen, and inner thighs) caused by one or more of the following factors: moisture, occlusion, chafing, continued contact with urine or feces or both, or mechanical or chemical irritation. Mild conditions appear as simple erythema. More severe conditions include papules, vesicles, oozing, and ulceration.

(f) Fever blister, cold sore. A vesicle that occurs at the junction of the mucous membrane and skin on the lips or nose and is caused by the virus herpes simplex, type 1.

[68 FR 33376, June 4, 2003; 55 FR 3362, Jan. 31, 1990; 55 FR 25204, June 20, 1990]

Part B—Active Ingredients

§ M016.10 Skin protectant active ingredients

The active ingredients of the product consist of any of the following, within the concentration specified for each ingredient:

(a) Allantoin, 0.5 to 2 percent.

(b) Aluminum hydroxide gel, 0.15 to 5 percent.

(c) Calamine, 1 to 25 percent.

(d) Cocoa butter, 50 to 100 percent.

(e) Cod liver oil, 5 to 13.56 percent, in accordance with § M016.20(a)(1), (a)(2), or (f), provided the product is labeled so that the quantity used in a 24-hour period does not exceed 10,000 United States Pharmacopeia (USP) Units vitamin A and 400 USP Units cholecalciferol.

(f) Colloidal oatmeal, 0.007 percent minimum; 0.003 percent minimum in combination with mineral oil in accordance with § M016.20(a)(4).

(g) Dimethicone, 1 to 30 percent.

(h) Glycerin, 20 to 45 percent.

(i) Hard fat, 50 to 100 percent.

(j) Kaolin, 4 to 20 percent.

(k) Lanolin, 12.5 to 50 percent.

(l) Mineral oil, 50 to 100 percent; 30 to 35 percent in combination with colloidal oatmeal in accordance with § M016.20(a)(4).

(m) Petrolatum, 30 to 100 percent.

(n) Lanolin, 15.5 percent in accordance with § M016.20(f).

(o) Sodium bicarbonate.

(p) Talc, 45 to 100 percent.

(q) Topical starch, 10 to 98 percent.

(r) White petrolatum, 30 to 100 percent.

(s) Zinc acetate, 0.1 to 2 percent.

(t) Zinc carbonate, 0.2 to 2 percent.

(u) Zinc oxide, 1 to 25 percent.

(v) Zinc oxide, above 25 to 40 percent in an ointment dosage form.

§ M016.12 Astringent active ingredients

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

(a) Aluminum acetate, 0.13 to 0.5 percent (depending on the formulation and concentration of the marketed product, the manufacturer must provide adequate directions so that the resulting solution to be used by the consumer contains 0.13 to 0.5 percent aluminum acetate).

(b) Aluminum sulfate, 46 to 63 percent (the concentration is based on the anhydrous equivalent).

(c) Witch hazel.

§ M016.20 Permitted combinations of active ingredients

(a) Combinations of skin protectant active ingredients.

(1) Any two or more of the ingredients identified in § M016.10(a), (d), (e), (i), (k), (l), (m), and (r) may be combined provided the combination is labeled according to § M016.50(b)(1) and provided each ingredient in the combination is within the concentration specified in § M016.10.

(2) Any two or more of the ingredients identified in § M016.10(a), (d), (e), (g), (h), (i), (k), (l), (m), and (r) may be combined provided the combination is labeled according to § M016.50(b)(2) and provided each ingredient in the combination is within the concentration specified in § M016.10.

(3) Any two or more of the ingredients identified in § M016.10(b), (c), (j), (s), (t), and (u) may be combined provided the combination is labeled according to § M016.50(b)(3) and provided each ingredient in the combination is within the concentration specified in § M016.10.

(4) The ingredients identified in § M016.10(f) and (l) may be combined provided the combination is labeled according to § M016.50(b)(7) and provided each ingredient in the combination is within the concentration specified in § M016.10.

(b) Combination of ingredients to prepare an aluminum acetate solution. Aluminum sulfate tetradecahydrate may be combined with calcium acetate monohydrate in powder or tablet form to provide a 0.13 to 0.5 percent aluminum acetate solution when the powder or tablet is dissolved in the volume of water specified in "Directions."

(c) Combinations of skin protectant and external analgesic active ingredients. Any one (two when required to be in combination) or more of the active ingredients identified in § M016.10(a), (d), (e), (i), (k), (l), (m), and (r) may be combined with any of the following generally recognized as safe and effective external analgesic active ingredients identified in § M017.10(a), (b), and (c) of OTC Monograph M017 (Single amine and "caine"-type local anesthetics, alcohols and ketones, antihistamines), or any permitted combination of these ingredients identified in § M017.20(a)(1), (2) or (3) of OTC Monograph M017, but not with hydrocortisone, provided the product is labeled according to § M016.60(b)(1).

(d) Combinations of skin protectant and first aid antiseptic active ingredients. Any one (two when required to be in combination) or more of the active ingredients identified in § M016.10(a), (d), (e), (i), (k), (l), (m), and (r) may be combined with any generally recognized as safe and effective single first aid antiseptic active ingredient identified in § M003.10 of OTC Monograph M003, or any permitted combination of these ingredients, provided the product is labeled according to § M016.60(b)(2).

(e) Combinations of skin protectant and sunscreen active ingredients. Any one (two when required to be in combination) or more of the skin protectant active ingredients identified in § M016.10(a), (d), (e), (g), (h), (i), (k), (l), (m), and (r) may be combined with any generally recognized as safe and effective single sunscreen active ingredient, provided the product meets the conditions in § M020.10; or any permitted combination of these ingredients, provided the product meets the conditions in § M020.20 of OTC Monograph M020; and is labeled according to § M016.60(b)(3) and § M020.50(c) of OTC Monograph M020.

(f) Combinations of skin protectant active ingredients for diaper rash. Any two or more of the ingredients identified in § M016.10(a), (c), (e), (g), (j), (l), (m), (n), (p), (q), (r), (u), and (v) may be combined provided the combination is labeled according to § M016.50(b)(8) and provided each ingredient in the combination is within the concentrations specified in § M016.10.

(g) Skin protectant and external analgesic combinations for fever blisters/cold sores. See § M017.20 of OTC Monograph M017.

[68 FR 33377, June 4, 2003, as amended at 74 FR 9765, Mar. 6, 2009; 55 FR 25204 June 20, 1990, 55 FR 3362 January 31, 1990]

Part C—Labeling

§ M016.50 Labeling of skin protectant drug products

A skin protectant drug product may have more than one labeled use and labeling appropriate to different uses may be combined to eliminate duplicative words or phrases as long as the labeling is clear and understandable. When the labeling of the product contains more than one labeled use, the appropriate statement(s) of identity, indications, warnings, and directions must be stated in the labeling.

(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:

(1) For any product. "Skin protectant" (optional, may add dosage form, e.g., "cream," "gel," "lotion," or "ointment").

(2) For any product formulated as a lip protectant. "Skin protectant," "lip protectant," or "lip balm" (optional, may add dosage form, e.g., "cream," "gel," "lotion," or "ointment").

(3) For products containing any ingredient in § M016.10(b), (c), (j), (s), (t), and (u). "Poison ivy, oak, sumac drying" (optional, may add dosage form, e.g., "cream," "gel," "lotion," or "ointment").

(4) For products containing any ingredient in § M016.10(b), (c), (f), (j), (o), (s), (t), and (u). "Poison ivy, oak, sumac protectant."

(5) For products containing any ingredient in § M016.10(a), (d), (g), (h), (m), and (r). "Fever blister/cold sore treatment."

(b) Indications. The labeling of the product states, under the heading "Uses," one or more of the phrases listed in § M016.50(b), as appropriate. Other truthful and nonmisleading statements, describing only the uses that have been established and listed in § M016.50(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 products containing any ingredient in §§ M016.10(a), (d), (e), (i), (k), (l), (m), and (r). The labeling states "temporarily protects minor: [bullet][4] cuts [bullet] scrapes [bullet] burns".

(2) For products containing any ingredient in § M016.10(a), (d), (e), (g), (h), (i), (k), (l), (m), and (r)

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

(i) The labeling states (optional: "helps prevent and") "temporarily protects" (optional: "and helps relieve") (optional: "chafed,") "chapped or cracked skin" (optional: "and lips"). This statement may be followed by the optional statement: "helps" (optional: "prevent and") "protect from the drying effects of wind and cold weather". [If both statements are used, each is preceded by a bullet.]

(ii) For products formulated as a lip protectant. The labeling states (optional: "helps prevent and") "temporarily protects" (optional: "and helps relieve") (optional: "chafed,") "chapped or cracked lips". This statement may be followed by the optional statement: "helps" (optional: "prevent and") "protect from the drying effects of wind and cold weather". [If both statements are used, each is preceded by a bullet.]

(3) For products containing any ingredient in § M016.10(b), (c), (j), (s), (t), and (u). The labeling states "dries the oozing and weeping of poison: [bullet] ivy [bullet] oak [bullet] sumac".

(4) For products containing colloidal oatmeal identified in § M016.10(f). The labeling states "temporarily protects and helps relieve minor skin irritation and itching due to: [select one or more of the following: ‘[bullet] rashes’ ‘[bullet] eczema’ ‘[bullet] poison ivy, oak, or sumac’ ‘[bullet] insect bites’."

(5) For products containing sodium bicarbonate identified in § M016.10(o). The labeling states "temporarily protects and helps relieve minor skin irritation and itching due to: [bullet] poison ivy, oak, or sumac [bullet] insect bites".

(6) For products containing topical starch identified in § M016.10(q). The labeling states "temporarily protects and helps relieve minor skin irritation".

(7) For products containing the combination of ingredients in § M016.20(a)(4). The labeling states "temporarily protects and helps relieve minor skin irritation and itching due to: [select one or more of the following: ‘rashes’ or ‘eczema’]". [If both conditions are used, each is preceded by a bullet.]

(8) For products containing any ingredient in § M016.10(a), (c), (e), (g), (j), (l), (m), (n), (p), (q), (r), (u), and (v). "Helps treat and prevent diaper rash. Protects" (select one of the following: "chafed skin" or "minor skin irritation") (select one of the following: "due to" or "associated with") "diaper rash and helps" (select one of the following: "protect from" or "seal out") "wetness."

(9) For products containing any ingredient in § M016.10(a), (d), (g), (h), (m), and (r). "Relieves dryness and softens cold sores and fever blisters," which may be followed by the optional statement, "Softens crusts (scabs) associated with cold sores and fever blisters."

(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). For products containing only mineral oil in § M016.10(l) or sodium bicarbonate in § M016.10(o), this warning may be omitted if labeling for oral use of the product is also provided.

(2) "When using this product [bullet] do not get into eyes".

(3) "Stop use and ask a doctor if [bullet] condition worsens [bullet] symptoms last more than 7 days or clear up and occur again within a few days".

(4) For products labeled according to § M016.50(b)(1) or (b)(2). "Do not use on [bullet] deep or puncture wounds [bullet] animal bites [bullet] serious burns".

(5) For products containing colloidal oatmeal identified in § M016.10(f) when labeled for use as a soak in a tub. "When using this product [bullet] to avoid slipping, use mat in tub or shower".

(6) For powder products containing kaolin identified in § M016.10(j) or topical starch identified in § M016.10(q)

(i) "Do not use on [bullet] broken skin".

(ii) "When using this product [bullet] keep away from face and mouth to avoid breathing it".

(7) For products containing colloidal oatmeal identified in § M016.10(f) or sodium bicarbonate identified in § M016.10(o) when labeled for use as a soak, compress, or wet dressing. "When using this product [bullet] in some skin conditions, soaking too long may overdry".

(8) For powder products containing kaolin identified in § M016.10(j), talc identified in § M016.10(p), or topical starch identified in § M016.10(q). "Do not use on broken skin. Keep powder away from child's face to avoid inhalation, which can cause breathing problems."

(d) Directions. The labeling of the product contains the following statements, as appropriate, under the heading "Directions":

(1) For products labeled according to § M016.50(b)(1), (b)(2), (b)(3), (b)(5), or (b)(6). The labeling states "apply as needed".

(2) For products containing colloidal oatmeal identified in § M016.10(f)

(i) For products requiring dispersal in water. The labeling states "[bullet] turn warm water faucet on to full force [bullet] slowly sprinkle" (manufacturer to insert quantity to be used) "of colloidal oatmeal directly under the faucet into the tub or container [bullet] stir any colloidal oatmeal settled on the bottom".

(A) For products used as a soak in a bath. The manufacturer must provide adequate directions to obtain a solution containing a minimum of 0.007 percent colloidal oatmeal or 0.003 percent colloidal oatmeal in the oilated form for a tub bath, sitz bath, or infant bath, or a minimum of 0.25 percent colloidal oatmeal for a foot bath. "For use as a soak in a bath: [bullet] soak affected area for 15 to 30 minutes as needed, or as directed by a doctor [bullet] pat dry (do not rub) to keep a thin layer on the skin".

(B) For products used as a compress or wet dressing. The manufacturer must provide adequate directions to obtain a solution containing a minimum of 0.25 percent colloidal oatmeal. "For use as a compress or wet dressing: [bullet] soak a clean, soft cloth in the mixture [bullet] apply cloth loosely to affected area for 15 to 30 minutes [bullet] repeat as needed or as directed by a doctor [bullet] discard mixture after each use".

(ii) For topical products intended for direct application. The labeling states "apply as needed".

(3) For products containing sodium bicarbonate identified in § M016.10(o). The labeling states "[bullet] adults and children 2 years of age and over:"

(i) The labeling states "For use as a paste: [bullet] add enough water to the sodium bicarbonate to form a paste [bullet] apply to the affected area of the skin as needed, or as directed by a doctor".

(ii) The labeling states "For use as a soak in a bath: [bullet] dissolve 1 to 2 cupfuls in a tub of warm water [bullet] soak for 10 to 30 minutes as needed, or as directed by a doctor [bullet] pat dry (do not rub) to keep a thin layer on the skin".

(iii) The labeling states "For use as a compress or wet dressing: [bullet] add sodium bicarbonate to water to make a mixture in a container [bullet] soak a clean, soft cloth in the mixture [bullet] apply cloth loosely to affected area for 15 to 30 minutes [bullet] repeat as needed or as directed by a doctor [bullet] discard mixture after each use".

(iv) Any of the directions in § M016.50(d)(3)(i), (d)(3)(ii), or (d)(3)(iii) shall be followed by the statement: "[bullet] children under 2 years: ask a doctor".

(4) For products containing aluminum hydroxide gel identified in § M016.10(b). The labeling states "[bullet] children under 6 months: ask a doctor".

(5) For products containing glycerin identified in § M016.10(h). The labeling states "[bullet] children under 6 months: ask a doctor".

(6) For products containing zinc acetate identified in § M016.10(s). The labeling states "[bullet] children under 2 years: ask a doctor".

(7) For products labeled according to § M016.50(b)(8)

(i) For all products. "Change wet and soiled diapers promptly, cleanse the diaper area, and allow to dry. Apply" (select one of the following: "ointment," "cream," "powder," or "product") "liberally as often as necessary, with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged."

(ii) For powder products only. "Apply powder close to the body away from child's face. Carefully shake the powder into the diaper or into the hand and apply to diaper area."

(e) Products formulated and labeled as a lip protectant and that meet the criteria established in 21 CFR 201.66(d)(10). The title, headings, subheadings, and information described in 21 CFR 201.66(c) shall be printed in accordance with the following specifications:

(1) The labeling shall meet the requirements of 21 CFR 201.66(c) except that the title, headings, and information described in § 201.66(c)(1), (c)(3), (c)(6), and (c)(7) may be omitted, and the headings, subheadings, and information described in § 201.66(c)(2), (c)(4), and (c)(5) may be presented as follows:

(i) The active ingredients (21 CFR 201.66(c)(2)) shall be listed in alphabetical order.

(ii) The heading and the indication required by 21 CFR 201.66(c)(4) may be limited to: "Use [in bold type] helps" (optional: "prevent and") "protect" (optional: "and relieve") "chapped lips". If both optional terms are used, the indication may be limited to: "Use [in bold type] helps prevent, protect, and relieve chapped lips".

(iii) The "external use only" warning in § M016.50(c)(1) and in 21 CFR 201.66(c)(5)(i) may be omitted. The warnings in M016.50(c)(2), (c)(3), and (c)(4) are not required.

(iv) The subheadings in 21 CFR 201.66(c)(5)(iii) through (c)(5)(vi) may be omitted, provided the information after the heading "Warning" contains the warning in § M016.50(e)(1)(iii).

(v) The warnings in 21 CFR 201.66(c)(5)(x) may be omitted.

(2) The labeling shall be printed in accordance with the requirements of 21 CFR 201.66(d) except that any requirements related to § 201.66(c)(1), (c)(3), (c)(6), and (c)(7), and the horizontal barlines and hairlines described in § 201.66(d)(8), may be omitted.

(f) Products containing only cocoa butter, petrolatum, or white petrolatum identified in § M016.10(d), (m), and (r), singly or in combination with each other, and marketed other than as a lip protectant.

(1) The labeling shall meet the requirements of 21 CFR 201.66(c) except that the headings and information described in § 201.66(c)(3) and (c)(7) may be omitted, and the headings, subheadings, and information described in § 201.66(c)(2), (c)(4), and (c)(5) may be presented as follows:

(i) The active ingredients (21 CFR 201.66(c)(2)) shall be listed in alphabetical order.

(ii) The heading and the indication required by 21 CFR 201.66(c)(4) may be limited to "Use [in bold type] helps protect minor cuts and burns" or "Use [in bold type] helps" (optional: "prevent and") "protect chapped skin" or "Use [in bold type] helps protect minor cuts and burns and" (optional: "prevent and protect") "chapped skin".

(iii) The warning in § M016.50(c)(3) may be revised to read "See a doctor if condition lasts more than 7 days."

(iv) The subheadings in 21 CFR 201.66(c)(5)(iv) through (c)(5)(vii) may be omitted, provided the information after the heading "Warnings" contains the warnings in § M016.50(c)(2), (c)(4), and (f)(1)(iii).

(2) The labeling shall be printed in accordance with the requirements of 21 CFR 201.66(d) except that any requirements related to § 201.66(c)(3) and (c)(7) may be omitted.

[68 FR 33377, June 4, 2003, as amended at 68 FR 68511, Dec. 9, 2003; 73 FR 6017, Feb. 1, 2008; 55 FR 3362, January 31, 1990; 55 FR 25204, June 20, 1990]

§ M016.52 Labeling of astringent 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 "astringent." For products containing the combination of aluminum sulfate tetradecahydrate and calcium acetate monohydrate identified in § M016.20(b), under the "Purpose" heading identified in 21 CFR 201.66(c)(3), the labeling of each active ingredient in the product states "Astringent*", which is followed by the statements "* When combined together in water, these ingredients form the active ingredient aluminum acetate. See [the following in bold italic type] Directions."

(b) Indications. The labeling of the product states, under the heading "Uses" any of the phrases listed in § M016.52(b), as appropriate. Other truthful and nonmisleading statements describing only the indications for use that have been established and listed in § M016.52(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 of 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) For products containing aluminum acetate identified in § M016.12(a) or the combination of aluminum sulfate tetradecahydrate and calcium acetate monohydrate identified in § M016.20(b). "For temporary relief of minor skin irritations due to: [select one or more of the following: ‘poison ivy,’ ‘poison oak,’ ‘poison sumac,’ ‘insect bites,’ ‘athlete's foot,’ or ‘rashes caused by soaps, detergents, cosmetics, or jewelry’]."

(2) For products containing aluminum sulfate identified in § M016.12(b) for use as a styptic pencil. "Stops bleeding caused by minor surface cuts and abrasions as may occur during shaving."

(3) For products containing witch hazel identified in § M016.12(c). "Relieves minor skin irritations due to: [select one or more of the following: ‘insect bites,’ ‘minor cuts,’ or ‘minor scrapes’]." [If more than one condition is used, each is preceded by a bullet.]

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

(1) For all products

(i) The labeling states "For external use only".

(ii) The labeling states "When using this product [bullet] avoid contact with eyes. If contact occurs, rinse thoroughly with water."

(2) For products containing aluminum acetate identified in§ M016.12(a), witch hazel identified in § M016.12(c), or the combination of aluminum sulfate tetradecahydrate and calcium acetate monohydrate identified in § M016.20(b). The labeling states "Stop use and ask a doctor if [bullet] condition worsens or symptoms last more than 7 days".

(3) For products containing aluminum acetate identified in § M016.12(a) or the combination of aluminum sulfate tetradecahydrate and calcium acetate monohydrate identified in § M016.20(b) when labeled for use as a compress or wet dressing. The labeling states "When using this product [bullet] do not cover compress or wet dressing with plastic to prevent evaporation".

(4) For products containing aluminum acetate identified in § M016.12(a) or the combination of aluminum sulfate tetradecahydrate and calcium acetate monohydrate identified in § M016.20(b) when labeled for use as a soak, compress, or wet dressing. The labeling states "When using this product [bullet] in some skin conditions, soaking too long may overdry".

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

(1) For products containing aluminum acetate identified in § M016.12(a) or the combination of aluminum sulfate tetradecahydrate and calcium acetate monohydrate identified in § M016.20(b)

(i) For products used as a soak. "For use as a soak: [preceding words in bold type] [bullet] soak affected area for 15 to 30 minutes as needed, or as directed by a doctor [bullet] repeat 3 times a day or as directed by a doctor [bullet] discard solution after each use".

(ii) For products used as a compress or wet dressing. "For use as a compress or wet dressing: [preceding words in bold type] [bullet] soak a clean, soft cloth in the solution [bullet] apply cloth loosely to affected area for 15 to 30 minutes [bullet] repeat as needed or as directed by a doctor [bullet] discard solution after each use".

(2) For products containing aluminum sulfate identified in § M016.12(b) for use as a styptic pencil. "Moisten tip of pencil with water and apply to the affected area. Dry pencil after use."

(3) For products containing witch hazel identified in § M016.12(c). "Apply as often as needed".

(4) For products containing the combination of aluminum sulfate tetradecahydrate and calcium acetate monohydrate identified in §M016.20(b)

(i) For powder dosage form. The labeling states "[bullet] dissolve 1 to 3 packets in [insert volume] of cool or warm water [bullet] stir until fully dissolved; do not strain or filter. The resulting mixture contains [insert percent] (1 packet), [insert percent] (2 packets), or [insert percent] (3 packets) aluminum acetate and is ready for use." These statements shall be the first statements under the heading "Directions".

(ii) For tablet dosage form. The labeling states "[bullet] dissolve 1 to 3 tablets in [insert volume] of cool or warm water [bullet] stir until fully dissolved; do not strain or filter. The resulting mixture contains [insert percent] (1 tablet), [insert percent] (2 tablets), or [insert percent] (3 tablets) aluminum acetate and is ready for use." These statements shall be the first statements under the heading "Directions".

(e) Products formulated and labeled as a styptic pencil and that meet the criteria established in 21 CFR 201.66(d)(10). The title, headings, subheadings, and information described in § 201.66(c) shall be printed in accordance with the following specifications:

(1) The labeling shall meet the requirements of 21 CFR 201.66(c) except that the headings and information described in § 201.66(c)(3) and (c)(7) may be omitted, and the headings, subheadings, and information described in § 201.66(c)(4) and (c)(5) may be presented as follows:

(i) The heading and indication required by 21 CFR 201.66(c)(4) may be limited to: "Use [in bold type] stops bleeding of minor cuts from shaving".

(ii) The "external use only" warning in § M016.52(c)(1) and in 21 CFR 201.66(c)(5)(i) may be omitted. The second warning in § M016.52(c)(1) may state: "avoid contact with eyes". The warning in 21 CFR 201.66(c)(5)(x) may be limited to the following: "Keep out of reach of children." The subheadings in § 201.66(c)(5)(iii) through (c)(5)(vii) may be omitted, provided the information after the heading "Warning" contains the warnings in § M016.52(e).

(2) The labeling shall be printed in accordance with the requirements of 21 CFR 201.66(d) except that any requirements related to § 201.66(c)(3) and (c)(7), and the horizontal barlines and hairlines described in § 201.66(d)(8), may be omitted.

[68 FR 33377, June 4, 2003, as amended at 68 FR 35293, June 13, 2003; 69 FR 3005, Jan. 22, 2004; 74 FR 9765, Mar. 6, 2009]

§ M016.60 Labeling of permitted combinations of active ingredients

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. For a combination drug product that does not have an established name, the labeling of the product states the statement of identity for each ingredient in the combination, as established in the statement of identity sections of the applicable OTC monographs.

(b) Indications. The labeling of the product states, under the heading "Uses," the indication(s) for each ingredient in the combination as established in the indications sections of the applicable OTC monographs, unless otherwise stated in § M016.60(b). Other truthful and nonmisleading statements, describing only the indications for use that have been established in the applicable OTC monographs or listed in § M016.60(b) may also be used, as provided in 21 CFR 330.1(c)(2), subject to the provisions of section 502 of 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. In addition to the required information identified in § M016.60(b), the labeling of the product may contain any of the "other allowable statements" that are identified in the applicable OTC monographs, provided such statements are neither placed in direct conjunction with information required to appear in the labeling nor occupy labeling space with greater prominence or conspicuousness than the required information.

(1) Combinations of skin protectant and external analgesic active ingredients in § M016.20(c). In addition to any or all of the indications for skin protectant drug products in § M016.50(b)(1), any or all of the allowable indications for external analgesic drug products may be used if the product is labeled for concurrent symptoms.

(2) Combinations of skin protectant and first aid antiseptic active ingredients in § M016.20(d). In addition to any or all of the indications for skin protectant drug products in § M016.50(b)(1), the required indications for first aid antiseptic drug products should be used.

(3) Combinations of skin protectant and sunscreen active ingredients in § M016.20(e). In addition to any or all of the indications for skin protectant drug products in § M016.50(b)(2)(i), the required indications for sunscreen drug products should be used and any or all of the additional indications for sunscreen drug products may be used.

(c) Warnings. The labeling of the product states, under the heading "Warnings," the warning(s) for each ingredient in the combination, as established in the warnings section of the applicable OTC monographs unless otherwise stated in § M016.60(c).

(1) For combinations containing a skin protectant and a sunscreen identified in § M016.20(e) . The warnings for sunscreen drug products in § M020.50(d) of OTC Monograph M020 are used.

(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 § M016.60(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) For combinations containing a skin protectant and a sunscreen identified in § M016.20(e). The directions for sunscreen drug products in § M020.50(e) of OTC Monograph M020 are used.