



U.S. Food and Drug Administration

Final Administrative Order (OTC000033):

Over-the-Counter Monograph M017: External Analgesic Drug Products for Over-the-Counter Human Use (Posted May 2, 2023)

I. Summary

Over-the-Counter Monograph M017: External Analgesic 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) of the FD&C Act are deemed to be generally recognized as safe and effective under section 201(p)(1) (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

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.

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 February 8, 1983 (48 FR 5852), FDA published a tentative final OTC monograph (TFM) under the procedure in part 330, that would establish conditions under which OTC external analgesic drug products are generally recognized as safe and effective (GRASE) (see also technical correction on March 11, 1983 (48 FR 10373)). In the *Federal Register* of June 19, 1992 (57 FR 27654), FDA issued a final OTC monograph under the procedure of part 330, establishing conditions under which OTC male genital desensitizing drug products (premature ejaculation remedies) are GRASE. This final OTC monograph was codified in 21 CFR part 348. FDA did not finalize any other GRASE conditions at that time for OTC external analgesic drug products.

In the *Federal Register* of July 30, 1986 (51 FR 27360), FDA issued a notice of proposed rulemaking in the form of an amended TFM to add indications for use in the symptomatic treatment of seborrheic dermatitis and psoriasis. FDA proposed to amend the TFM to include warnings and directions for OTC hydrocortisone-containing external analgesic drug products labeled for “external anal itching” (53 FR 32592, August 25, 1988). FDA proposed to amend the TFM with the conditions under which OTC external analgesic drug products for the treatment of the symptoms of poison ivy, poison oak, poison sumac dermatitis and insect bites would be GRASE when the final monograph became effective (54 FR 40818, October 3, 1989). In the *Federal Register* of January 31, 1990 (55 FR 3370), FDA published a proposed rule to amend the TFM to establish the conditions under which OTC external analgesic drug products for the treatment of fever blisters and cold sores are GRASE (see also technical correction on March 27, 1990 (55 FR 11291)). FDA again proposed to amend the TFM with the conditions under which OTC external analgesic products containing hydrocortisone or its hydrocortisone acetate equivalent for topical use in concentrations from 0.25 to 1% would be GRASE (55 FR 6932, February 27, 1990).

In the *Federal Register* of August 30, 1991 (56 FR 43025), FDA announced an enforcement policy with respect to OTC marketing of external analgesic drug products containing above 0.5 up to 1% hydrocortisone or hydrocortisone acetate equivalent pending FDA’s anticipated determination that these products would be GRASE. FDA also revised the labeling for OTC hydrocortisone products proposed in the amended TFM. FDA proposed to amend the TFM to add warnings to advise consumers not to use topical products containing diphenhydramine on chicken pox, poison ivy, sunburn, large areas of the body, blistered or oozing skin, more often than directed, or with any other product containing diphenhydramine, even one taken by mouth (62 FR 45767, August 29, 1997). Finally, in the *Federal Register* of July 17, 2003 (68 FR

42324), FDA amended the TFM to clarify the status of patch, plaster, and poultice dosage forms for OTC external analgesic drug products. FDA classified all OTC external analgesic ingredients in a patch, plaster, or poultice dosage form as Category III (more data needed).

Accordingly, this final order for OTC external analgesic drug products incorporates the requirements of the final monograph for OTC external analgesic drug products issued under part 330, as codified in part 348 as of March 27, 2020 and the proposed rules issued in the *Federal Register* on February 8, 1983 (48 FR 5852), July 30, 1986 (51 FR 27360), August 25, 1988 (53 FR 32592), October 3, 1989 (54 FR 40818), January 31, 1990 (55 FR 3370), February 27, 1990 (55 FR 6932), August 30, 1991 (56 FR 43025), August 29, 1997 (62 FR 45767), and July 17, 2003 (68 FR 42324), with technical amendments.

III. Final Administrative Order

Over-the-Counter Monograph M017:

External Analgesic Drug Products for Over-the-Counter Human Use

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SOURCE: 57 FR 27656, June 19, 1992, unless otherwise noted.

Part A—General Provisions

§ M017.1 Scope

An over-the-counter (OTC) external analgesic 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.

§ M017.3 Definitions

As used in this OTC monograph:

- (a) Analgesic, anesthetic. A topically (externally) applied drug that relieves pain by depressing cutaneous sensory receptors.
- (b) Antipruritic. A topically (externally) applied drug that relieves itching by depressing cutaneous sensory receptors.
- (c) Camphorated metacresol. A complex consisting of camphor and metacresol combined in a ratio of 3 parts camphor to 1 part metacresol.
- (d) Counterirritant. A topically (externally) applied drug that causes irritation or mild inflammation of the skin for the purpose of relieving pain in muscles, joints, or viscera distal to the site of application by stimulating cutaneous sensory receptors.
- (e) External analgesic. A topically (externally) applied drug that has a topical analgesic, anesthetic, or antipruritic effect by depressing cutaneous sensory receptors, or that has a topical counterirritant effect by stimulating cutaneous sensory receptors.
- (f) Male genital desensitizing drug product. A drug product applied to the penis to help in temporarily slowing the onset of ejaculation.
- (g) Poison ivy, poison oak, or poison sumac dermatitis. An allergic contact dermatitis (usually an intensely itching skin rash) due to exposure to plants of the genus *Rhus* (poison ivy, poison oak, poison sumac), which contain urushiol, a potent skin-sensitizing agent.
- (h) 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.

[48 FR 5852, Feb. 8, 1983; 54 FR 40818, Oct. 03, 1989; 55 FR 3370, Jan. 31, 1990]

Part B - Active Ingredients

§ M017.10 Analgesic, anesthetic, and antipruritic active ingredients

The active ingredients of the product consist of any of the following, within the established concentration for each ingredient, but not for use in a patch, plaster, or poultice dosage form:

- (a) Amine and “caine”-type local anesthetics.
 - (1) Benzocaine 5 to 20%.
 - (2) Butamben picrate 1%.

- (3) Dibucaine 0.25 to 1%.
- (4) Dibucaine hydrochloride 0.25 to 1%.
- (5) Dimethisoquin hydrochloride 0.3 to 0.5%.
- (6) Dyclonine hydrochloride 0.5 to 1%.
- (7) Lidocaine 0.5 to 4%.
- (8) Lidocaine hydrochloride 0.5 to 4%.
- (9) Pramoxine hydrochloride 0.5 to 1%.
- (10) Tetracaine 1 to 2%.
- (11) Tetracaine hydrochloride 1 to 2%.

(b) Alcohols and ketones.

- (1) Benzyl alcohol 10 to 33%.
- (2) Camphor 0.1 to 3%.
- (3) Camphor 3 to 10.8% when combined with phenol in accordance with § M017.20(a)(4).
- (4) Camphorated metacresol (camphor 3 to 10.8% and metacresol 1 to 3.6%).
- (5) Juniper tar 1 to 5%.
- (6) Menthol 0.1 to 1%.
- (7) Phenol 0.5 to 1.5%.
- (8) Phenol 4.7% when combined with camphor in accordance with § M017.20(a)(4).
- (9) Phenolate sodium 0.5 to 1.5%.
- (10) Resorcinol 0.5 to 3%.

(c) Antihistamines.

- (1) Diphenhydramine hydrochloride 1 to 2%.
- (2) Tripeleminamine hydrochloride 0.5 to 2%.

(d) Hydrocortisone preparations.

- (1) Hydrocortisone 0.25 to 1%.
- (2) Hydrocortisone acetate, equivalent to hydrocortisone, 0.25 to 1%.

(e) Male genital desensitizers.

- (1) Benzocaine, 3 to 7.5% in a water-soluble base.
- (2) Lidocaine in a metered spray with approximately 10 milligrams per spray.

[48 FR 5852, Feb. 8, 1983; 55 FR 6932, Feb. 27, 1990]

§ M017.12 Counterirritant active ingredients

The active ingredients of the product consist of any of the following, within the established concentration for each ingredient, but not for use in a patch, plaster, or poultice dosage form:

(a) Irritants that produce redness.

- (1) Allyl isothiocyanate 0.5 to 5%.
- (2) Strong ammonia solution, diluted to contain 1 to 2.5% ammonia.
- (3) Methyl salicylate 10 to 60%.
- (4) Turpentine oil 6 to 50%.

(b) Irritants that produce cooling sensation.

- (1) Camphor exceeding 3% to 11%.
- (2) Menthol 1.25 to 16%.

(c) Irritants that produce vasodilation.

- (1) Histamine dihydrochloride 0.025 to 0.10%.
- (2) Methyl nicotinate 0.25 to 1%.

(d) Irritants that do not produce redness.

- (1) Capsaicin 0.025 to 0.25%.

(2) Capsicum containing 0.025 to 0.25% capsaicin.

(3) Capsicum oleoresin containing 0.025 to 0.25% capsaicin.

[48 FR 5852, Feb. 8, 1983; 68 FR 42324, Jul. 17, 2003]

§ M017.20 Permitted combinations of active ingredients

(a) Combinations of external analgesic active ingredients.

(1) Any ingredient identified in § M017.10(a) may be combined with any ingredient identified in § M017.10(b).

(2) Any ingredient identified in § M017.10(b) may be combined with any ingredient in § M017.10(c).

(3) Any ingredient identified in §§ M017.10(b)(1), (5), (7), (9), and (10) may be combined with camphor and menthol identified in §§ M017.10(b)(2) and (6).

(4) Camphor and phenol identified in §§ M017.10(b)(3) and (8) may be combined in a light mineral oil, United States Pharmacopeia (USP) vehicle.

(5) Any two, three, or four ingredients identified in § M017.12 may be combined provided that the combination contains no more than one active ingredient from each group identified in §§ M017.12(a), (b), (c), and (d).

(6) Camphor identified in § M017.12(b)(1) may be combined with menthol identified in § M017.12(b)(2).

(7) Camphor and menthol identified in § M017.20(a)(6) may be combined with any one, two, or three ingredients identified in § M017.12 provided the combination contains no more than one ingredient from each group identified in §§ M017.12(a), (c), and (d).

(b) Combinations of external analgesic active ingredients and other active ingredients.

(1) Any ingredient identified in §§ M017.10(a), (b), or (c) (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), but not hydrocortisone, may be combined with any one (two when required to be in combination) or more of the generally recognized safe and effective skin protectant active ingredients or skin protectant combinations identified in §§ M016.10(a), (d), (e), (i), (k), (l), (m), and (r) in OTC Monograph M016 provided the product is labeled for the concurrent symptoms.

(2) Any single ingredient identified in § M017.10(a) may be combined with any single generally recognized safe and effective first aid antiseptic active ingredient identified in

§ M003.10 of OTC Monograph M003, provided the product is labeled in accordance with § M003.60 of OTC Monograph M003.

(3) Any single ingredient identified in § M017.10(a) may be combined with first aid antibiotic active ingredients identified in § M004.20(b) of OTC Monograph M004, provided the product is labeled in accordance with § M004.60 of OTC Monograph M004.

(4) Any ingredient identified in § M017.10 (a) or (b) or any combination identified in § M017.20(a) (1) or (3) may be combined with any generally recognized safe and effective skin protectant active ingredient identified in § M016.10 of OTC Monograph M016 or skin protectant combination identified in § M016.20(a) of OTC Monograph M016 for treatment of fever blisters and cold sores provided the product is labeled according to § M017.52.

[48 FR 5852, Feb. 8, 1983; 55 FR 3370, Jan. 31, 1990]

Part C—Labeling

§ M017.50 Labeling of external analgesic 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 follows:

(1) For products containing any ingredient identified in § M017.10(a), (b), and (c) and § M017.12. The labeling identifies the product as an “external analgesic,” “topical analgesic,” or “pain relieving (insert dosage form, e.g., cream, lotion, or ointment).”

(2) For products containing hydrocortisone or hydrocortisone acetate identified in § M017.10(d). “Antipruritic (anti-itch),” “anti-itch,” “antipruritic (anti-itch) (insert dosage form, e.g., cream, lotion, ointment, or spray),” or “anti-itch (insert dosage form, e.g., cream, lotion, or spray).”

(3) For products containing any ingredient identified in § M017.10(e). “Male genital desensitizer.”

(4) For products containing any ingredient in §§ M017.10(a) or (b). “Fever blister/cold sore treatment.”

(b) Indications. The labeling of the product states, under the heading “Uses,” any of the phrases listed in § M017.50(b) as appropriate. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in § M017.50(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 external analgesic active ingredients identified in § M017.12. “For the temporary relief of minor aches and pains of muscles and joints” [which may be followed by: “associated with” (select one or more of the following: “simple backache,” “arthritis,” “strains,” “bruises,” and “sprains”)].

(2) For products containing any external analgesic active ingredients identified in §§ M017.10(a), (b), and (c). “For the temporary relief of” (select one of the following: “pain,” “itching,” or “pain and itching”) (which may be followed by: “associated with” (select one or more of the following: “minor burns,” “sunburn,” “minor cuts,” “scrapes,” “insect bites,” “minor skin irritations,” (optional, may include the following: “rashes due to”) “poison ivy,” “poison oak,” or “poison sumac”)).

(3) For products containing any external analgesic active ingredients identified in § M017.10(d).

(i) One of the following should be used:

(A) “For the temporary relief of itching associated with minor skin irritations and rashes” [which may be followed by: “due to” (select one or more of the following: “eczema,” “insect bites,” “poison ivy, poison oak, or poison sumac,” “soaps,” “detergents,” “cosmetics,” “jewelry,” “seborrheic dermatitis,” “psoriasis”) and/or (“and for external” (select one or more of the following: “genital,” “feminine,” and “anal”) “itching”)]; or

(B) “For the temporary relief of itching associated with minor skin irritations, inflammation, and rashes due to” (select one or more of the following: “eczema,” “insect bites,” “poison ivy, poison oak, or poison sumac,” “soaps,” “detergents,” “cosmetics,” “jewelry,” “seborrheic dermatitis,” “psoriasis”) and/or (“and for external” (select one or more of the following: “genital,” “feminine,” and “anal”) “itching”).

(ii) “Other uses of this product should be only under the advice and supervision of a” (select one of the following: “physician” or “doctor”).

(4) Other allowable statements. In addition to the required information specified in §§ M017.50(a), (b), (c), and (d), the labeling of the product may contain any of the following statements, as appropriate for the product’s formulation, 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.

(i) For products containing any ingredient identified in § M017.12.

(A) (optional: “provides”) “penetrating pain relief.”

(B) (optional: “provides”) “warming pain relief.”

(C) (optional: “provides”) “cooling pain relief.”

(5) For products containing any external analgesic active ingredients identified in §§ M017.10(a) and (b). “For the temporary relief of” (select one of the following: “pain,” “itching,” or “pain and itching”) (which may be followed by: “associated with” (select one or more of the following: “fever blisters,” “cold sores,” or “fever blisters and cold sores”)).

(6) For products containing any ingredient identified in § M017.10(e).

(i) “Helps in the prevention of premature ejaculation.”

(ii) “For temporary male genital desensitization, helping to slow the onset of ejaculation.”

(iii) “Helps in temporarily” (select one of the following: “retarding the onset of,” “slowing the onset of,” or “prolonging the time until”) followed by “ejaculation.”

(iv) “For reducing oversensitivity in the male in advance of intercourse.”

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

(1) For products containing any external analgesic active ingredient identified in §§ M017.10(a), (b), and (c) and § M017.12.

(i) “For external use only.”

(ii) “Avoid contact with the eyes.”

(iii) “If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and consult a” (select one of the following: “physician” or “doctor”).

(2) For products containing any external analgesic active ingredient identified in § M017.12.

(i) “Do not apply to wounds or damaged skin.”

(ii) “Do not bandage tightly.”

(3) For products containing butamben picrate identified in § M017.10(a)(2).

(i) “Do not apply over large areas of the body.”

(ii) “This product stains skin and clothing yellow.”

(4) For products containing any external analgesic active ingredient identified in §§ M017.10(a)(3), (4), (7), (8), (10), and (11). “Do not use in large quantities, particularly over raw surfaces or blistered areas.”

(5) For products containing camphorated metacresol identified in § M017.10(b)(4), phenol identified in §§ M017.10(b)(7) and (8), and phenolate sodium identified in § M017.10(b)(9). “Do not apply over large areas of the body or bandage.”

(6) For products containing resorcinol identified in § M017.10(b)(10). “Do not apply over large areas of the body.”

(7) For products containing hydrocortisone preparations identified in §§ M017.10(d)(1) and (2).

(i) “For external use only.”

(ii) “Avoid contact with the eyes.”

(iii) “If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, stop use of this product and do not begin use of any other hydrocortisone product unless you have consulted a (select one of the following: “physician” or “doctor”).”

(iv) “Do not use for the treatment of diaper rash. Consult a (select one of the following: “Physician” or “doctor”).”

(v) If the product is labeled with the indications “for external genital itching,” or “for external feminine itching,” the warnings must include the statement: “Do not use if you have a vaginal discharge. Consult a (select one of the following: “physician” or “doctor”).”

(vi) If the product is labeled with the indication “for external anal itching,” the warnings must include the following statements: “Do not exceed the recommended daily dosage unless directed by a doctor. In case of bleeding, consult a doctor promptly. Do not put this product into the rectum by using fingers or any mechanical device or applicator.” (The word “physician” may be substituted for the word “doctor” in these statements.)

(8) For products containing diphenhydramine hydrochloride identified in § M017.10(c)(1). The following statement shall appear as the first warning statement under the heading “Warnings:” “Do Not Use:” (these three words in bold print) “on chicken pox, poison ivy, sunburn, large areas of the body, broken, blistered, or oozing skin, more often than directed, or with any other product containing diphenhydramine, even one taken by mouth.”

(9) For products containing any ingredient identified in § M017.10(e).

(i) “Premature ejaculation may be due to a condition requiring medical supervision. If this product, used as directed, does not provide relief, discontinue use and consult a doctor.”

(ii) “Avoid contact with the eyes.”

(iii) “If you or your partner develop a rash or irritation, such as burning or itching, discontinue use. If symptoms persist, consult a doctor.”

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

(1) For products containing any external analgesic active ingredient identified in §§ M017.10(a), (b), and (c) § M017.12. Adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily. Children under 2 years of age: do not use, consult a (select one of the following: physician or doctor).

(2) For products containing hydrocortisone preparations identified in §§ M017.10(d)(1) and (2).

(i) Adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily. Children under 2 years of age: Do not use, consult a (select one of the following: physician or doctor).

(ii) If the product is labeled with the indication “for external anal itching,” the directions must include the following statements: “Adults: When practical, cleanse the affected area” (select one or both of the following: “with mild soap and warm water and rinse thoroughly” or “by patting or blotting with an appropriate cleansing pad”). “Gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product.” (Other appropriate directions in § M017.50 may be inserted here.) “Children under 12 years of age: consult a” (select one of the following: “physician” or doctor”).

(3) For products containing any ingredient identified in § M017.10(e).

(i) For products containing benzocaine identified in § M017.10(e)(1). “Apply a small amount to head and shaft of penis before intercourse, or use as directed by a doctor. Wash product off after intercourse.”

(ii) For products containing lidocaine identified in § M017.10(e)(2). “Apply 3 or more sprays, not to exceed 10, to head and shaft of penis before intercourse, or use as directed by a doctor. Wash product off after intercourse.”

(e) The word “physician” may be substituted for the word “doctor” in any of the labeling statements in § M017.50.

[48 FR 5852, Feb. 8, 1983; 51 FR 27360, Jul. 30, 1986; 54 FR 40818, Oct. 3, 1989; 55 FR 3370, Jan. 31, 1990; 55 FR 6932, Feb. 27, 1990; 56 FR 43025, Aug. 30, 1991; 62 FR 45767, Aug. 29, 1997]

§ M017.52 Labeling of permitted combinations

Statements 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 § M017.52(b). Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in the applicable OTC monographs, 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 states, under the heading “Warnings,” the warning(s) for each ingredient in the combination, as established in the Warnings sections of the applicable OTC monographs.

(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. When the time intervals or age limitations for administration of the individual ingredients differ, the directions for the combination product may not exceed any maximum dosage limits established for the individual ingredients in the applicable OTC monograph.

[55 FR 3370, Jan. 31, 1990]