

§ 341.40

- (2) Pseudoephedrine hydrochloride.
- (3) Pseudoephedrine sulfate.
- (4) Phenylephrine bitartrate in an effervescent dosage form.
- (b) *Topical nasal decongestants.* (1) Levmetamfetamine.
 - (2) Ephedrine.
 - (3) Ephedrine hydrochloride.
 - (4) Ephedrine sulfate.
 - (5) [Reserved]
 - (6) Naphazoline hydrochloride.
 - (7) Oxymetazoline hydrochloride.
 - (8) Phenylephrine hydrochloride.
 - (9) Propylhexedrine.
 - (10) Xylometazoline hydrochloride.

[59 FR 43409, Aug. 23, 1994, as amended at 63 FR 40650, July 30, 1998; 71 FR 43362, Aug. 1, 2006]

§ 341.40 Permitted combinations of active ingredients.

The following combinations are permitted provided each active ingredient is present within the dosage limits established in parts 341, 343, and 356 of this chapter and the product is labeled in accordance with §§ 341.70 or 341.85:

(a) Any single antihistamine active ingredient identified in § 341.12 may be combined with any generally recognized as safe and effective single analgesic-antipyretic active ingredient, or any combination of acetaminophen with other analgesic-antipyretic active ingredients, or any aspirin and antacid combination provided that the product is labeled according to § 341.85.

(b) Any single antihistamine active ingredient identified in § 341.12 may be combined with any single oral nasal decongestant active ingredient identified in § 341.20(a) provided that the product is labeled according to § 341.85.

(c) Any single antihistamine active ingredient identified in § 341.12 may be combined with any single oral nasal decongestant active ingredient identified in § 341.20(a) and any generally recognized as safe and effective single analgesic-antipyretic active ingredient, or any combination of acetaminophen with other analgesic-antipyretic active ingredients, or any aspirin and antacid combination provided that the product is labeled according to § 341.85.

(d) Any single antihistamine active ingredient identified in § 341.12(a) through (e) and (h) through (m) may be combined with any single oral

21 CFR Ch. I (4–1–11 Edition)

antitussive active ingredient identified in § 341.14(a)(1) through (a)(4) provided that the product is labeled according to § 341.85(c)(4). Diphenhydramine citrate in §§ 341.12(f) and 341.14(a)(5) or diphenhydramine hydrochloride in §§ 341.12(g) and 341.14(a)(6) may be both the antihistamine and the antitussive active ingredient provided that the product is labeled according to § 341.70(a).

(e) Any single antihistamine active ingredient identified in § 341.12(a) through (e) and (h) through (m) may be combined with any single oral antitussive active ingredient identified in § 341.14(a)(1) through (a)(4) and any single oral nasal decongestant active ingredient identified in § 341.20(a) provided that the product is labeled according to § 341.85(c)(4). Diphenhydramine citrate in §§ 341.12(f) and 341.14(a)(5) or diphenhydramine hydrochloride in §§ 341.12(g) and 341.14(a)(6) may be both the antihistamine and the antitussive active ingredient provided that the product is labeled according to § 341.70(a).

(f) Any single antihistamine active ingredient identified in § 341.12(a) through (e) and (h) through (m) may be combined with any single oral antitussive active ingredient identified in § 341.14(a)(1) through (a)(4) and any generally recognized as safe and effective single analgesic-antipyretic active ingredient, or any combination of acetaminophen with other analgesic-antipyretic active ingredients, or any aspirin and antacid combination provided that the product is labeled according to § 341.85(c)(4). Diphenhydramine citrate in §§ 341.12(f) and 341.14(a)(5) or diphenhydramine hydrochloride in §§ 341.12(g) and 341.14(a)(6) may be both the antihistamine and the antitussive active ingredient provided that the product is labeled according to § 341.70(a).

(g) Any single antihistamine active ingredient identified in § 341.12(a) through (e) and (h) through (m) may be combined with any single oral antitussive active ingredient identified in § 341.14(a)(1) through (a)(4) and any single oral nasal decongestant active ingredient identified in § 341.20(a) and

any generally recognized as safe and effective single analgesic-antipyretic active ingredient, or any combination of acetaminophen with other analgesic-antipyretic active ingredients, or any aspirin and antacid combination provided that the product is labeled according to § 341.85(c)(4). Diphenhydramine citrate in §§ 341.12(f) and 341.14(a)(5) or diphenhydramine hydrochloride in §§ 341.12(g) and 341.14(a)(6) may be both the antihistamine and the antitussive active ingredient provided that the product is labeled according to § 341.70(a).

(h) Any single oral antitussive active ingredient identified in § 341.14(a)(1) through (a)(4) may be combined with any single expectorant active ingredient identified in § 341.18 provided that the product is labeled according to § 341.85.

(i) Any single oral antitussive active ingredient identified in § 341.14(a) may be combined with any single oral nasal decongestant active ingredient identified in § 341.20(a) provided that the product is labeled according to § 341.85.

(j) Any single oral antitussive active ingredient identified in § 341.14(a)(1) through (a)(4) may be combined with any single oral nasal decongestant active ingredient identified in § 341.20(a) and any single expectorant active ingredient identified in § 341.18 provided that the product is labeled according to § 341.85.

(k) Any single antitussive active ingredient identified in § 341.14(a) or (b)(2) may be combined with any generally recognized as safe and effective single oral anesthetic/analgesic active ingredient, or any combination of anesthetic/analgesic active ingredients provided that the product is available in either a liquid (to be swallowed) or a solid dosage form (to be dissolved in the mouth and swallowed) and provided that the product is labeled according to § 341.85. If the combination contains a topical antitussive, the product must be formulated in a solid dosage form to be dissolved in the mouth. Menthol in § 341.14(b)(2) and part 356 of this chapter may be both the antitussive and the anesthetic/analgesic active ingredient provided that the product is labeled according to § 341.70(b).

(l) Any single oral antitussive active ingredient identified in § 341.14(a) may be combined with any generally recognized as safe and effective single analgesic-antipyretic active ingredient, or any combination of acetaminophen with other analgesic-antipyretic active ingredients, or any aspirin and antacid combination provided that the product is labeled according to § 341.85.

(m) Any single oral antitussive active ingredient identified in § 341.14(a) may be combined with any single oral nasal decongestant active ingredient identified in § 341.20(a) and any generally recognized as safe and effective single analgesic-antipyretic active ingredient, or any combination of acetaminophen with other analgesic-antipyretic active ingredients, or any aspirin and antacid combination provided that the product is labeled according to § 341.85.

(n) Any single oral antitussive active ingredient identified in § 341.14(a)(1) through (a)(4) may be combined with any single oral nasal decongestant active ingredient identified in § 341.20(a) and any single expectorant active ingredient identified in § 341.18 and any generally recognized as safe and effective single analgesic-antipyretic active ingredient, or any combination of acetaminophen with other analgesic-antipyretic active ingredients, or any aspirin and antacid combination provided that the product is labeled according to § 341.85.

(o) Any single expectorant active ingredient identified in § 341.18 may be combined with any generally recognized as safe and effective single analgesic-antipyretic active ingredient, or any combination of acetaminophen with other analgesic-antipyretic active ingredients, or any aspirin and antacid combination provided that the product is labeled according to § 341.85.

(p) Any single expectorant active ingredient identified in § 341.18 may be combined with any single oral nasal decongestant active ingredient identified in § 341.20(a) provided that the product is labeled according to § 341.85.

(q) Any single expectorant active ingredient identified in § 341.18 may be combined with any single oral nasal decongestant active ingredient identified

§ 341.40**21 CFR Ch. I (4–1–11 Edition)**

in §341.20(a) and any generally recognized as safe and effective single analgesic-antipyretic active ingredient, or any combination of acetaminophen with other analgesic-antipyretic active ingredients, or any aspirin and antacid combination provided that the product is labeled according to §341.85.

(r) Any single oral nasal decongestant active ingredient identified in §341.20(a) may be combined with any generally recognized as safe and effective single analgesic-antipyretic active ingredient, or any combination of acetaminophen with other analgesic-antipyretic active ingredients, or any aspirin and antacid combination provided that the product is labeled according to §341.85.

(s) Any single oral nasal decongestant active ingredient identified in §341.20(a) may be combined with any generally recognized as safe and effective single oral anesthetic/analgesic active ingredient identified, or any combination of anesthetic/analgesic active ingredients provided that the product is available in either a liquid (to be swallowed) or a solid dosage form (to be dissolved in the mouth and swallowed) and provided that the product is labeled according to §341.85.

(t) Any single oral nasal decongestant active ingredient identified in §341.20(a) may be combined with any single antitussive active ingredient identified in §341.14(a) or (b)(2) and any generally recognized as safe and effective single oral anesthetic/analgesic active ingredient, or any combination of anesthetic/analgesic active ingredients provided that the product is available in either a liquid (to be swallowed) or a solid dosage form (to be dissolved in the mouth and swallowed) and provided that the product is labeled according to §341.85. If the combination contains a topical antitussive, the product must be formulated in a solid dosage form to be dissolved in the mouth.

(u) Camphor identified in §341.14(b)(1) may be combined with menthol identified in §341.14(b)(2) and eucalyptus oil (1.2 to 1.3 percent) provided that the product is available only in a suitable ointment vehicle and provided that the product is labeled according to §341.85.

(v) Levmetamfetamine identified in §341.20(b)(1) may be combined with aro-

matics (camphor (54 milligrams (mg)), menthol (80 mg), methyl salicylate (11 mg), and lavender oil (4 mg)) provided that the product is available only as a nasal inhaler and provided that the product is labeled according to §341.85.

(w) Any single antitussive active ingredient identified in §341.14(a) or (b)(2) may be combined with any generally recognized as safe and effective single oral demulcent active ingredient provided that the product is available in either a liquid (to be swallowed) or a solid dosage form (to be dissolved in the mouth and swallowed) and provided that the product is labeled according to §341.85. If the combination contains a topical antitussive, the product must be formulated in a solid dosage form to be dissolved in the mouth.

(x) Any single oral nasal decongestant active ingredient identified in §341.20(a) may be combined with any generally recognized as safe and effective single oral demulcent active ingredient provided that the product is available in either a liquid (to be swallowed) or a solid dosage form (to be dissolved in the mouth and swallowed) and provided that the product is labeled according to §341.85.

(y) Any single antitussive active ingredient identified in §341.14(a) or (b)(2) may be combined with any single oral nasal decongestant active ingredient identified in §341.20(a) and any generally recognized as safe and effective single oral demulcent active ingredient provided that the product is available in either a liquid (to be swallowed) or a solid dosage form (to be dissolved in the mouth and swallowed) and provided that the product is labeled according to §341.85. If the combination contains a topical antitussive, the product must be formulated in a solid dosage form to be dissolved in the mouth.

(z) Any single antitussive active ingredient identified in §341.14(a) or (b)(2) may be combined with any generally recognized as safe and effective single oral anesthetic/analgesic active ingredient or any combination of anesthetic/analgesic active ingredients and any generally recognized as safe and effective single oral demulcent active ingredient provided that the product is

available in either a liquid (to be swallowed) or a solid dosage form (to be dissolved in the mouth and swallowed) and provided that the product is labeled according to § 341.85. If the combination contains a topical antitussive, the product must be formulated in a solid dosage form to be dissolved in the mouth.

(aa) Any single oral nasal decongestant active ingredient identified in § 341.20(a) may be combined with any generally recognized as safe and effective single oral anesthetic/analgesic active ingredient or any combination of oral anesthetic/analgesic active ingredients and any generally recognized as safe and effective single oral demulcent active ingredient provided that the product is available in either a liquid (to be swallowed) or a solid dosage form (to be dissolved in the mouth and swallowed) and provided that the product is labeled according to § 341.85.

(bb) Any single antitussive active ingredient identified in § 341.14(a) or (b)(2) may be combined with any single oral nasal decongestant active ingredient identified in § 341.20(a) and any generally recognized as safe and effective single oral anesthetic/analgesic active ingredient identified or any combination of anesthetic/analgesic active ingredients and any generally recognized as safe and effective single oral demulcent active ingredient provided that the product is available in either a liquid (to be swallowed) or a solid dosage form (to be dissolved in the mouth and swallowed) and provided that the product is labeled according to § 341.85. If the combination contains a topical antitussive, the product must be formulated in a solid dosage form to be dissolved in the mouth.

[67 FR 78168, Dec. 23, 2002]

Subpart C—Labeling

§ 341.70 Labeling of OTC drug products containing ingredients that are used for treating concurrent symptoms (in either a single-ingredient or combination drug product).

The 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) *For products containing diphenhydramine citrate and diphenhydramine hydrochloride identified in § 341.14(a)(5) and (a)(6).* The labeling of the product contains the established name of the drug, if any, and identifies the product as an “antihistamine/cough suppressant” or “antihistamine/antitussive (cough suppressant).” The indications shall be combined from §§ 341.72(b) and 341.74(b). The warnings shall be combined from §§ 341.72(c)(1), (c)(2), (c)(4), and (c)(6) and 341.74(c)(1), (c)(2), (c)(3), and (c)(4). Alternatively, all of the warnings in § 341.74(c) shall be used. The directions for OTC labeling shall follow §§ 341.74(d)(1)(iv) or (d)(1)(v), as applicable. The directions for professional labeling shall follow § 341.90(j) or (k), as applicable.

(b) *For products containing menthol identified in §§ 341.14(b)(2) and 356.12(f) of this chapter.* The product contains 5 to 10 milligrams menthol. The labeling of the product contains the established name of the drug, if any, and identifies the product as a “cough suppressant/oral anesthetic” or “antitussive (cough suppressant)/oral anesthetic.” The indications shall be combined from § 341.74(b) and part 356 of this chapter. The warnings shall be combined from § 341.74(c)(1), (c)(2), and (c)(3) and part 356 of this chapter. The directions shall be: “Directions [in bold type] [bullet]¹ adults and children 2 years and over: dissolve lozenge slowly in the mouth. Repeat every 2 hours as needed or as directed by a doctor. [bullet] children under 2 years of age: ask a doctor”.

[61 FR 15703, Apr. 9, 1996, as amended at 67 FR 78170, Dec. 23, 2002; 68 FR 17881, Apr. 14, 2003]

§ 341.72 Labeling of antihistamine 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 “antihistamine.”

(b) *Indications.* The labeling of the product states, under the heading “Indications,” any of the phrases listed in

¹See § 201.66(b)(4) of this chapter for definition of bullet symbol.