(5) Diphenhydramine citrate.
(6) Diphenhydramine hydrochloride.
(b) *Topical antitussives.* (1) Camphor.
(2) Menthol.

[52 FR 30055, Aug. 12, 1987, as amended at 59 FR 29174, June 3, 1994; 67 FR 4907, Feb. 1, 2002]

§ 341.16 Bronchodilator active ingredients.

The active ingredients of the product consist of any of the following when used within the dosage limits established for each ingredient:
(a) Ephedrine.
(b) Ephedrine hydrochloride.
(c) Ephedrine sulfate.
(d) Epinephrine.
(e) Epinephrine bitartrate.
(f) Racephedrine hydrochloride.
(g) Racepinephrine hydrochloride.

[51 FR 35339, Oct. 2, 1986]

§ 341.18 Expectorant active ingredient.

The active ingredient of the product is guaifenesin when used within the dosage limits established in § 341.78(d).

[54 FR 8509, Feb. 28, 1989]

§ 341.20 Nasal decongestant active ingredients.

The active ingredient of the product consists of any of the following when used within the dosage limits and in the dosage forms established for each ingredient:
(a) *Oral nasal decongestants.* (1) Phenylephrine hydrochloride.
(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 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 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 aromatics (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*