

- (b) *Topical antitussives.*
- (1) Camphor.
- (2) Menthol.

[52 FR 30055, Aug. 12, 1987, as amended at 59 FR 29174, June 3, 1994]

**§ 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.
- (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]

**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) (Reserved)

[61 FR 15703, Apr. 9, 1996]

**§ 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 paragraph (b) of this section, as appropriate. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in this paragraph, may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the