(d) **Expectorant drug.** A drug taken orally to promote or facilitate the removal of secretions from the respiratory airways.

(e) **Antihistamine drug.** A drug used for the relief of the symptoms of hay fever and upper respiratory allergies (allergic rhinitis).

(f) **Oral nasal decongestant drug.** A drug that is taken by mouth and acts systemically to reduce nasal congestion caused by acute or chronic rhinitis.

(g) **Topical nasal decongestant drug.** A drug that when applied topically inside the nose, in the form of drops, jellies, or sprays, or when inhaled intranasally reduces nasal congestion caused by acute or chronic rhinitis.

(h) **Calibrated dropper.** A dropper calibrated such that the volume error incurred in measuring any liquid does not exceed 15 percent under normal use conditions.

(i) **Effervescent dosage form.** A dosage form intended to be dissolved in water before administration. It contains, in addition to the active ingredient(s), mixtures of acids (citric acid, tartaric acid) and sodium bicarbonate, which release carbon dioxide when dissolved in water.


**Subpart B—Active Ingredients**

### § 341.12 Antihistamine active ingredients.

The active ingredient of the product consists of any of the following when used within the dosage limits established for each ingredient:

(a) Brompheniramine maleate.

(b) Chlorcyclizine hydrochloride.

(c) Chlorpheniramine maleate.

(d) Dextromethorphan.

(e) Dextromethorphan hydrobromide.

(f) Diphenhydramine citrate.

(g) Diphenhydramine hydrochloride.

(h) Doxylamine succinate.

(i) Phenindamine tartrate.

(j) Pheniramine maleate.

(k) Pyrilamine maleate.

(l) Thonzylamine hydrochloride.

(m) Triprolidine hydrochloride.

[57 FR 58374, Dec. 9, 1992, as amended at 59 FR 4218, Jan. 28, 1994]

### § 341.14 Antitussive active ingredients.

The active ingredients of the product consist of any of the following when used within the dosage limits and in the dosage forms established for each ingredient in § 341.7(d):

(a) **Oral antitussives.** (1) Chlophedianol hydrochloride.

(2) Codeine ingredients. The following ingredients may be used only in combination in accordance with §§ 200.2 and 21 CFR 1308.15(c):

(i) Codeine.

(ii) Codeine phosphate.

(iii) Codeine sulfate.

(3) Dextromethorphan.

(4) Dextromethorphan hydrobromide.

(5) Diphenhydramine citrate.

(6) Diphenhydramine hydrochloride.

(b) **Topical antitussives.** (1) Camphor.

(2) Menthol.


### § 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) Ractopamine hydrochloride.

(g) Ractopamine hydrochloride.

[51 FR 33339, 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) Ractopamine hydrochloride.