Subpart A—General Provisions

§ 341.1 Scope.

(a) An over-the-counter cold, cough, allergy, bronchodilator, or anti-asthmatic drug product in a form suitable for oral, inhalant, or topical administration is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this part and each of the general conditions established in § 330.1.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

[51 FR 35339, Oct. 2, 1986]

§ 341.3 Definitions.

As used in this part:

(a) Bronchodilator drug. A drug used to overcome spasms that cause narrowing of the bronchial air tubes, such as in the symptomatic treatment of the wheezing and shortness of breath of asthma.

(b) Oral antitussive drug. A drug that either is taken by mouth or is dissolved in the mouth in the form of a lozenge and acts systemically to relieve cough.

(c) Topical antitussive drug. A drug that relieves cough when inhaled after being applied topically inside the nose, in the form of drops, jellies, or sprays, or when dissolved in the mouth in the form of a lozenge for a local effect.

(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 hydrobromide.

(e) Diphenhydramine citrate.

(f) Diphenhydramine hydrochloride.

(g) Doxylamine succinate.

(h) Phenindamine tartrate.

(i) 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 § 341.74(d):

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

(2) Codeine ingredients. The following ingredients may be used only in combination in accordance with §§ 290.2 and 21 CFR 1308.15(c).

(i) Codeine.

(ii) Codeine phosphate.

(iii) Codeine sulfate.

(3) Dextromethorphan.

(4) Dextromethorphan hydrobromide.
§ 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 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(g) 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) and any generally recognized as safe and effective single analgesic-antipyretic active ingredient identified in §341.15(a)(1) through (a)(4) or any single oral decongestant active ingredient identified in §341.20(a) and any generally recognized as safe and effective single analgesic-antipyretic active ingredient identified in §341.15(a)(1) through (a)(4) if the product is labeled according to §341.85(c)(4) provided that the product is labeled according to §341.70(a).