

Food and Drug Administration, HHS

§ 341.3

age and over: Oral dosage is 100 to 200 milligrams not more often than every 3 to 4 hours.

PART 341—COLD, COUGH, ALLERGY, BRONCHODILATOR, AND ANTI-ASTHMATIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

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EDITORIAL NOTE: Nomenclature changes to part 341 appear at 69 FR 13717, Mar. 24, 2004.

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 condi-

tions 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 to the throat or chest in the form of an ointment or from a steam vaporizer, 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