§ 340.50

Subpart C—Labeling

§ 340.50 Labeling of stimulant 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 “alertness aid” or a “stimulant.”

(b) Indications. The labeling of the product states, under the heading “Indications,” the following: “Helps restore mental alertness or wakefulness when experiencing fatigue or drowsiness.” Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in this paragraph (b), may also be used, as provided in §330.1(c)(2), subject to the provisions of section 502 of the Act relating to misbranding and the prohibition in section 301(d) of the Act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the Act.

(c) Warnings. The labeling of the product contains the following warnings under the heading “Warnings”:

(1) “The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heart beat.”

(2) “For occasional use only. Not intended for use as a substitute for sleep. If fatigue or drowsiness persists or continues to recur, consult a” (select one of the following: “physician” or “doctor”).

(3) “Do not give to children under 12 years of age.”

(d) Directions. The labeling of the product contains the following information under the heading “Directions”: Adults and children 12 years of age and over: Oral dosage is 100 to 200 milligrams not more often than every 3 to 4 hours.
§ 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 is either 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.

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) Chlorpheniramine maleate.
(c) Chlorpheniramine maleate.
(d) Dextromethorphan hydrobromide.
(e) Doxylamine succinate.
(f) Dihydrocodeine tartrate.
(g) Phenindamine tartrate.
(h) Phenyldiphenhydramine tartrate.
(i) Pheniramine maleate.
(j) Pyrilamine maleate.
(k) Triprolidine hydrochloride.

§ 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 §341.24(d):
(a) Oral antitussives. (1) Chlorpheniramine maleate.
(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) Epinephrine.
(c) Ephedrine sulfate.
(d) Epinephrine.
(e) Epinephrine bitartrate.
(f) Racephedrine hydrochloride.
(g) Racepinephrine hydrochloride.

§ 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) Ephedrine.
   (2) Ephedrine hydrochloride.
   (3) Ephedrine sulfate.
   (4) Naphazoline hydrochloride.
   (5) Oxymetazoline hydrochloride.
   (6) Phenylephrine hydrochloride.
   (7) Propylhexedrine.
   (8) Xylometazoline hydrochloride.

[59 FR 43409, Aug. 23, 1994]

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.

(b) For products containing diphenhydramine citrate and diphenhydramine hydrochloride identified in §§341.72(c)(1) or (d)(1)(v), as applicable. The directions for OTC labeling shall follow §§341.72(d)(1)(i) or (d)(1)(v), as applicable. The directions for professional labeling shall follow §341.90(j) or (k), as applicable.

§ 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.

(1) “Temporarily” (select one of the following: “relieves,” “alleviates,” “decreases,” “reduces,” or “dries”) “runny nose and” (select one of the following: “relieves,” “alleviates,” “decreases,” or “reduces”) “sneezing, itching of the nose or throat, and itchy, watery eyes due to hay fever” (which may be followed by one or both of the following: “or other upper respiratory allergies” or “(allergic rhinitis)”).

(2) “For the temporary relief of runny nose, sneezing, itching of the nose or throat, and itchy, watery eyes due to hay fever” (which may be followed by one or both of the following: “or other upper respiratory allergies” or “(allergic rhinitis)”).

(c) Warnings. The labeling of the product contains the following warnings, under the heading “Warnings”:

(1) “May cause excitability especially in children.”
(2) “Do not take this product, unless directed by a doctor, if you have a...
breathing problem such as emphysema or chronic bronchitis, or if you have glaucoma or difficulty in urination due to enlargement of the prostate gland.”

(3) For products containing brompheniramine maleate, chlortyline hydrochloride, chlorpheniramine maleate, dexbrompheniramine maleate, dextropheniramine maleate, phenindamine tartrate, pheniramine maleate, pyrilamine maleate, thonzylamine hydrochloride, or triprolidine hydrochloride identified in §341.12(a), (c), (d), (e), (i), (j), (k), (l), and (m). “May cause drowsiness. Sedatives and tranquilizers may increase the drowsiness effect. Do not give this product to children who are taking sedatives or tranquilizers, without first consulting the child’s doctor.”

(iii) For products containing diphenhydramine citrate, diphenhydramine hydrochloride, or doxylamine succinate identified in §341.12(f), (g), and (h). “May cause marked drowsiness. Sedatives and tranquilizers may increase the drowsiness effect. Do not give this product to children who are taking sedatives or tranquilizers, without first consulting the child’s doctor.”

(d) Directions. The labeling of the product contains the following information under the heading “Directions”:

(1) For products containing brompheniramine maleate identified in §341.12(a). Adults and children 12 years of age and over: oral dosage is 4 milligrams every 4 to 6 hours, not to exceed 24 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: oral dosage is 2 milligrams every 4 to 6 hours, not to exceed 12 milligrams in 24 hours, or as directed by a doctor. Children under 6 years of age: consult a doctor.

(2) For products containing chlorpheniramine maleate identified in §341.12(b). Adults and children 12 years of age and over: oral dosage is 25 milligrams every 6 to 8 hours, not to exceed 75 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: oral dosage is 2 milligrams every 6 to 8 hours, not to exceed 12 milligrams in 24 hours, or as directed by a doctor. Children under 6 years of age: consult a doctor.

(3) For products containing chlorpheniramine maleate identified in §341.12(c). Adults and children 12 years of age and over: oral dosage is 4 milligrams every 4 to 6 hours, not to exceed 24 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: oral dosage is 2 milligrams every 4 to 6 hours, not to exceed 12 milligrams in 24 hours, or as directed by a doctor. Children under 6 years of age: consult a doctor.

(4) For products containing dexbrompheniramine maleate identified in §341.12(d). Adults and children 12 years of age and over: oral dosage is 4 milligrams every 4 to 6 hours, not to exceed 24 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: oral dosage is 2 milligrams every 4 to 6 hours, not to exceed 12 milligrams in 24 hours, or as directed by a doctor. Children under 6 years of age: consult a doctor.
§ 341.72

of age and over: oral dosage is 2 milligrams every 4 to 6 hours, not to exceed 12 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: oral dosage is 1 milligram every 4 to 6 hours, not to exceed 6 milligrams in 24 hours, or as directed by a doctor. Children under 6 years of age: consult a doctor.

(5) For products containing dexchlorpheniramine maleate identified in §341.12(e). Adults and children 12 years of age and over: oral dosage is 2 milligrams every 4 to 6 hours, not to exceed 12 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: oral dosage is 1 milligram every 4 to 6 hours, not to exceed 6 milligrams in 24 hours, or as directed by a doctor. Children under 6 years of age: consult a doctor.

(6) For products containing diphenhydramine citrate identified in §341.12(f). Adults and children 12 years of age and over: oral dosage is 38 to 76 milligrams every 4 to 6 hours, not to exceed 456 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: oral dosage is 19 to 38 milligrams every 4 to 6 hours, not to exceed 228 milligrams in 24 hours, or as directed by a doctor. Children under 6 years of age: consult a doctor.

(7) For products containing diphenhydramine hydrochloride identified in §341.12(g). Adults and children 12 years of age and over: oral dosage is 25 to 50 milligrams every 4 to 6 hours, not to exceed 300 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: oral dosage is 12.5 to 25 milligrams every 4 to 6 hours, not to exceed 150 milligrams in 24 hours, or as directed by a doctor. Children under 6 years of age: consult a doctor.

(8) For products containing doxylamine succinate identified in §341.12(h). Adults and children 12 years of age and over: oral dosage is 7.5 to 12.5 milligrams every 4 to 6 hours, not to exceed 75 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: oral dosage is 3.75 to 6.25 milligrams every 4 to 6 hours, not to exceed 37.5 milligrams in 24 hours, or as directed by a doctor. Children under 6 years of age: consult a doctor.

(9) For products containing phenindamine tartrate identified in §341.12(i). Adults and children 12 years of age and over: oral dosage is 25 milligrams every 4 to 6 hours, not to exceed 150 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: oral dosage is 12.5 milligrams every 4 to 6 hours, not to exceed 75 milligrams in 24 hours, or as directed by a doctor. Children under 6 years of age: consult a doctor.

(10) For products containing pheniramine maleate identified in §341.12(j). Adults and children 12 years of age and over: oral dosage is 12.5 to 25 milligrams every 4 to 6 hours, not to exceed 150 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: oral dosage is 6.25 to 12.5 milligrams every 4 to 6 hours, not to exceed 75 milligrams in 24 hours, or as directed by a doctor. Children under 6 years of age: consult a doctor.

(11) For products containing pyrilamine maleate identified in §341.12(k). Adults and children 12 years of age and over: oral dosage is 25 to 50 milligrams every 6 to 8 hours, not to exceed 200 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: oral dosage is 12.5 to 25 milligrams every 6 to 8 hours, not to exceed 100 milligrams in 24 hours, or as directed by a doctor. Children under 6 years of age: consult a doctor.

(12) For products containing thonzylamine hydrochloride identified in §341.12(l). Adults and children 12 years of age and over: oral dosage is 2.5 milligrams every 4 to 6 hours, not to exceed 10 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: oral dosage is 1.25 milligrams every 4 to 6 hours, not to exceed 5 milligrams in 24 hours, or as directed by a doctor.
§ 341.74 Labeling of antitussive 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 a “cough suppressant” or an “antitussive (cough suppressant).”

(b) Indications. The labeling of the product states, under the heading “Indications,” any of the phrases listed in this paragraph (b), 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), subject to the provisions of section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) “Temporarily” (select one of the following: “alleviates,” “calms,” “controls,” “decreases,” “quiets,” “reduces,” “relieves,” or “suppresses”) “cough due to” (select one of the following: “minor bronchial irritation” or “minor throat and bronchial irritation”) (select one of the following: “as may occur with,” “associated with,” or “occurring with”) (select one of the following: “A cold” or “the common cold”) “or inhaled irritants.”

(2) “Temporarily” (select one of the following: “alleviates,” “calms,” “controls,” “decreases,” “quiets,” “reduces,” “relieves,” or “suppresses”) “cough” (select one of the following: “as may occur with,” “associated with,” or “occurring with”) (select one of the following: “A cold,” “the common cold,” or “inhaled irritants”).

(i) “Cough suppressant which temporarily” (select one of the following: “alleviates,” “controls,” “decreases,” “reduces,” “relieves,” or “suppresses”) “the impulse to cough.”

(ii) “Temporarily helps you cough less.”

(iii) “Temporarily helps to” (select one of the following: “Alleviate,” “control,” “decrease,” “reduce,” “relieve,” or “suppress”) “the cough reflex that causes coughing.”

(iv) “Temporarily” (select one of the following: “Alleviates,” “controls,” “decreases,” “reduces,” “relieves,” or “suppresses”) “the intensity of coughing.”

(v) Select one of the following: “Alleviates,” “Controls,” “Decreases,” “Reduces,” “Relieves,” or “Suppresses”) (select one of the following: “Cough,” “the impulse to cough,” or “your cough”) “to help you” (select one of the following: “Get to sleep,” “sleep,” or “rest”).

(vi) For products containing chlophedianol hydrochloride, codeine ingredients, dextromethorphan, or dextromethorphan hydrobromide identified in §341.14(a) (1), (2), (3), and (4). “Calms the cough control center and relieves coughing.”

(vii) For products containing chlophedianol hydrochloride, dextromethorphan, dextromethorphan hydrobromide, camphor, or menthol identified in §341.14(a) (1), (3), (4) and (b) (1) and (2). (a) “Nonnarcotic cough suppressant for the temporary” (select one of the following: “alleviation,” “control,” “decrease,” “reduction,” “relief,” or “suppression”) “of cough.”

(b) (Select one of the following: “Alleviates,” “Controls,” “Decreases,” “Reduces,” “Relieves,” or “Suppresses”) “cough impulses without narcotics.”

(c) Warnings. The labeling of the product contains the following warnings under the heading “Warnings”:

(1) For oral and topical antitussives. “A persistent cough may be a sign of a serious condition. If cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache, consult a doctor.”

(2) For oral and topical antitussives labeled for adults or for adults and children under 12 years of age. “Do not take this
§ 341.74

21 CFR Ch. I (4-1-98 Edition)

product for persistent or chronic cough such as occurs with smoking, asthma, or emphysema, or if cough is accompanied by excessive phlegm (mucus) unless directed by a doctor."

(3) For oral and topical antitussives labeled only for children under 12 years of age. "Do not give this product for persistent or chronic cough such as occurs with asthma or if cough is accompanied by excessive phlegm (mucus) unless directed by a doctor."

(4) Oral antitussives—

(i) For products containing codeine ingredients identified in § 341.14(a)(2). "May cause or aggravate constipation."

(ii) For products containing codeine ingredients identified in § 341.14(a)(2) when labeled only for adults. "Do not take this product if you have a chronic pulmonary disease or shortness of breath unless directed by a doctor."

(iii) For products containing codeine ingredients identified in § 341.14(a)(2) when labeled only for children under 12 years of age. "Do not give this product to children who have a chronic pulmonary disease, shortness of breath, or who are taking other drugs unless directed by a doctor."

(iv) For products containing codeine ingredients identified in § 341.14(a)(2) when labeled for use in adults and children under 12 years of age. "Adults and children who have a chronic pulmonary disease or shortness of breath, or children who are taking other drugs, should not take this product unless directed by a doctor."

(v) For products containing dextromethorphan or dextromethorphan hydrobromide as identified in § 341.14(a)(3) and (a)(4) when labeled only for children under 12 years of age. "Drug interaction precaution. Do not give this product to a child who is taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions), or for 2 weeks after stopping the MAOI drug. If you are uncertain whether your child’s prescription drug contains an MAOI, consult a health professional before giving this product."

(vi) For products containing dextromethorphan or dextromethorphan hydrobromide as identified in § 341.14(a)(3) and (a)(4) when labeled only for children under 12 years of age. "Drug interaction precaution. Do not give this product to a child who is taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions), or for 2 weeks after stopping the MAOI drug. If you are uncertain whether your child’s prescription drug contains an MAOI, consult a health professional before giving this product."

(vii) For products containing diphenhydramine citrate or diphenhydramine hydrochloride identified in § 341.14(a)(5) and (a)(6). "May cause excitability especially in children."

(viii) For products containing diphenhydramine citrate or diphenhydramine hydrochloride identified in § 341.14(a)(5) and (a)(6) when labeled only for children under 12 years of age—

(A) "Do not give this product to children who have a breathing problem such as chronic bronchitis, or who have glaucoma, without first consulting the child’s doctor."

(B) "May cause marked drowsiness. Sedatives and tranquillizers may increase the drowsiness effect. Do not give this product to children who are taking sedatives or tranquillizers, without first consulting the child’s doctor."

(ix) For products containing diphenhydramine citrate or diphenhydramine hydrochloride identified in § 341.14(a)(5) and (a)(6) when labeled for use in adults and children under 12 years of age—

(A) "Do not take this product, unless directed by a doctor, if you have a breathing problem such as emphysema or chronic bronchitis, or if you have glaucoma or difficulty in urination due to enlargement of the prostate gland."

(B) "May cause marked drowsiness; alcohol, sedatives, and tranquillizers may increase the drowsiness effect. Avoid alcoholic beverages while taking this product. Do not take this product if you are taking sedatives or tranquillizers, without first consulting your doctor. Use caution when driving a motor vehicle or operating machinery."
(5) Topical antitussives—(i) For products containing camphor or menthol identified in §341.14(b) (1) and (2) in a suitable ointment vehicle. “For external use only. Do not take by mouth or place in nostrils.”

(ii) For products containing camphor or menthol identified in §341.14(b) (1) and (2) for steam inhalation use. “For steam inhalation only. Do not take by mouth.”

(d) Directions. The labeling of the product contains the following information under the heading “Directions”:

(1) Oral antitussives—(i) For products containing chlophedianol hydrochloride identified in §341.14(a)(1). Adults and children 12 years of age and over: Oral dosage is 25 milligrams every 6 to 8 hours, not to exceed 100 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: Oral dosage is 12.5 milligrams every 6 to 8 hours, not to exceed 50 milligrams in 24 hours, or as directed by a doctor. Children under 6 years of age: Consult a doctor.

(ii) For products containing codeine ingredients identified in §341.14(a)(2). Adults and children 12 years of age and over: Oral dosage is 10 to 20 milligrams every 4 to 6 hours, not to exceed 120 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: Oral dosage is 5 to 10 milligrams every 4 to 6 hours, not to exceed 60 milligrams in 24 hours, or as directed by a doctor. A special measuring device should be used to give an accurate dose of this product to children under 6 years of age. Giving a higher dose than recommended by a doctor could result in serious side effects for your child.

(iii) For products containing dextromethorphan or dextromethorphan hydrobromide identified in §341.14(a) (3) and (4). The dosage is equivalent to dextromethorphan hydrobromide. Adults and children 12 years of age and over: Oral dosage is 5 to 10 milligrams every 4 hours or 30 milligrams every 6 to 8 hours, not to exceed 120 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: Oral dosage is 5 to 10 milligrams every 4 hours or 15 milligrams every 6 to 8 hours, not to exceed 60 milligrams in 24 hours, or as directed by a doctor.

(iv) For products containing diphenhydramine citrate identified in §341.14(a)(5). Adults and children 12 years of age and over: Oral dosage is 38 milligrams every 4 hours, not to exceed 228 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: Oral dosage is 19 milligrams every 4 hours, not to exceed 114 milligrams in 24 hours, or as directed by a doctor. Children under 6 years of age: Consult a doctor.

(v) For products containing diphenhydramine hydrochloride identified in §341.14(a)(6). Adults and children 12 years of age and over: Oral dosage is 25 milligrams every 4 hours, not to exceed 150 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: Oral dosage is 12.5 milligrams every 4 hours, not to exceed 75 milligrams in 24 hours, or as directed by a doctor. Children under 6 years of age: consult a doctor.

(2) Topical antitussives—(i) For products containing camphor identified in §341.14(b) (1) in a suitable ointment vehicle. The product contains 4.7 to 5.3 percent camphor. Adults and children 2 to under 12 years of age: Rub on the throat and chest as a thick layer. The area of application may be covered with a warm, dry cloth if desired. However, clothing should be left loose about the throat and chest to help the vapors rise to reach the nose and mouth. Applications may be repeated up to three times daily or as directed by a doctor. Children under 2 years of age: consult a doctor.

(ii) For products containing menthol identified in §341.14(b)(2) in a suitable ointment vehicle. The product contains 2.6 to 2.8 percent menthol. Adults and children 2 to under 12 years of age: Rub on the throat and chest as a thick layer. The area of application may be covered with a warm, dry cloth if desired. However, clothing should be left loose about the throat and chest to help the vapors rise to reach the nose and mouth.
and mouth. Applications may be repeated up to three times daily or as directed by a doctor. Children under 2 years of age: consult a doctor.

(iii) For products containing menthol identified in §341.14(b)(2) in a lozenge. The product contains 5 to 10 milligrams menthol. Adults and children 2 to under 12 years of age: Allow lozenge to dissolve slowly in the mouth. May be repeated every hour as needed or as directed by a doctor. Children under 2 years of age: consult a doctor.

(iv) For products containing camphor identified in §341.14(b)(1) for steam inhalation use.

The product contains 6.2 percent camphor. Adults and children 2 to under 12 years of age: Add 1 tablespoonful of solution, for each quart of water, directly to the water in a hot steam vaporizer, bowl, or wash basin; or add 1½ teaspoonsful of solution, for each pint of water, to an open container of boiling water. Breathe in the medicated vapors. May be repeated up to three times daily or as directed by a doctor. Children under 2 years of age: consult a doctor.

(v) For products containing menthol identified in §341.14(b)(2) for steam inhalation use. The product contains 3.2 percent menthol. Adults and children 2 to under 12 years of age: Add 1 tablespoonful of solution, for each quart of water, directly to the water in a hot steam vaporizer, bowl, or wash basin; or add 1½ teaspoonsful of solution, for each pint of water, to an open container of boiling water. Breathe in the medicated vapors. May be repeated up to three times daily or as directed by a doctor. Children under 2 years of age: consult a doctor.

(e) The word "physician" may be substituted for the word "doctor" in any of the labeling statements in this section.

(f) Exemption from the general accidental overdose warning. The labeling for antitussive drug products containing the active ingredient identified in §341.14(b)(2) marketed in accordance with §341.74(d)(2)(iii) is exempt from the requirement in §330.1(g) of this chapter that the labeling bear the general warning statement "In case of accidental overdose, seek professional assistance or contact a poison control center immediately." The labeling must continue to bear the first part of the general warning in §330.1(g) of this chapter, which states, “Keep this and all drugs out of the reach of children.”

§ 341.76 Labeling of bronchodilator 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 a "bronchodilator."

(b) Indications. The labeling of the product states, under the heading "Indications," the phrase listed in paragraph (b)(1) of this section. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in this paragraph (b), may also be used, as provided in §330.1(c)(2), subject to the provisions of section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) "For temporary relief of shortness of breath, tightness of chest, and wheezing due to bronchial asthma."

(2) In addition to the required information identified in paragraph (b)(1) of this section, the labeling of the product may contain one or more of the following statements:

(i) "For the" (select one of the following: "temporary relief" or "symptomatic control") "of bronchial asthma."

(ii) "Eases breathing for asthma patients" (which may be followed by: "by reducing spasms of bronchial muscles").

(c) Warnings. The labeling of the product contains the following warnings under the heading "Warnings":

(1) "Do not use this product unless a diagnosis of asthma has been made by a doctor."

(2) "Do not use this product if you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland unless directed by a doctor."
§ 341.78 Labeling of expectorant 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 “expectorant.”

(b) Indications. The labeling of the product states, under the heading “Indications,” the following: “Helps loosen phlegm (mucus) and thin bronchial secretions to,” (select one or more of the following: “rid the bronchial passageways of bothersome mucus,” “drain bronchial tubes,” and “make coughs more productive”). Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in this paragraph (b), may also be used, as provided in §330.1(c)(2) of this chapter, subject to the provisions of section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(c) Warnings. The labeling of the product contains the following warnings, under the heading “Warnings”:

D. Directions. The labeling of the product contains the following information under the heading “Directions”:

1. For products containing ephedrine, ephedrine hydrochloride, ephedrine sulfate, or racephedrine hydrochloride identified in §341.16 (a), (b), (c), and (f). Adults and children 12 years of age and over: Oral dosage is 12.5 to 25 milligrams every 4 hours, not to exceed 150 milligrams in 24 hours, or as directed by a doctor. Do not exceed recommended dose unless directed by a doctor. Children under 12 years of age: Consult a doctor.

(2) For products containing epinephrine, epinephrine bitartrate, and racepinephrine hydrochloride identified in §341.16(d), (e), and (g) for use in a hand-held rubber bulb nebulizer. The ingredient is used in an aqueous solution at a concentration equivalent to 1 percent epinephrine. Inhalation dosage for adults, children 12 years of age and over, and children 4 to under 12 years of age: 1 to 3 inhalations not more often than every 3 hours. The use of this product by children should be supervised by an adult. Children under 4 years of age: Consult a doctor.

(Collection of information requirement approved by the Office of Management and Budget under control number 0910-0237)
§ 341.80  Labeling of nasal decongestant 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 a "nasal decongestant."

(b) Indications. The labeling of the product states, under the heading "Indications," the phrase listed in paragraph (b)(1) of this section, as appropriate, and may contain any additional phrases listed in paragraph (b)(2) of this section. Other truthful and non-misleading statements, describing only the indications for use that have been established and listed in paragraphs (b)(1) and (b)(2) of this section, 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 prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) (Select one of the following: "For the temporary relief of nasal congestion" or "Temporarily relieves nasal congestion") (which may be followed by any of the following in paragraphs (b)(1)(i), (ii), and (iii) of this section):

(i) "due to" (select one of the following: "the common cold" or "a cold").

(ii) "due to" (select one of the following: "hay fever," "hay fever (allergic rhinitis)," "hay fever or other upper respiratory allergies," or "hay fever or other upper respiratory allergies (allergic rhinitis)").

(iii) "associated with sinusitis."

(2) In addition to the information identified in paragraph (b)(1) of this section, the labeling of the product may contain any (one or more) of the following statements:

(i) (Select one of the following: "For the temporary relief of" or "Temporarily relieves") (select one of the following: "stuffy nose," "stopped up nose," "nasal stuffiness," or "clogged up nose.")

(ii) (Select one of the following: "Reduces swelling of," "Decongests," or "Helps clear") "nasal passages; shrinks swollen membranes."

(iii) "Temporarily restores freer breathing through the nose."

(iv) "Helps decongest sinus openings and passages; temporarily relieves sinus congestion and pressure."

(v) "Promotes nasal and/or sinus drainage; temporarily relieves sinus congestion and pressure."

(c) Warnings. The labeling of the product contains the following warnings under the heading "Warnings":

(1) Oral nasal decongestants—(i) For products containing phenylephrine hydrochloride, pseudoephedrine hydrochloride, or pseudoephedrine sulfate identified in §341.20 (a)(1), (a)(2), and (a)(3) when labeled for adults. (A) "Do not exceed..."
If nervousness, dizziness, or sleeplessness occur, discontinue use and consult a doctor."

(B) "If symptoms do not improve within 7 days or are accompanied by fever, consult a doctor."

(C) "Do not take this product if you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland unless directed by a doctor."

(D) "Drug interaction precaution. Do not use this product if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you are uncertain whether your prescription drug contains an MAOI, consult a health professional before taking this product."

(ii) For products containing phenylephrine hydrochloride, pseudoephedrine hydrochloride, or pseudoephedrine sulfate identified in § 341.20(a)(1), (a)(2), and (a)(3) when labeled for children under 12 years of age.

(A) "Do not exceed recommended dosage. [first sentence in boldface type] If nervousness, dizziness, or sleeplessness occur, discontinue use and consult a doctor."

(B) "If symptoms do not improve within 7 days or are accompanied by fever, consult a doctor."

(C) "Do not give this product to a child who has heart disease, high blood pressure, thyroid disease, or diabetes unless directed by a doctor."

(D) "Drug interaction precaution. Do not give this product to a child who is taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions), or for 2 weeks after stopping the MAOI drug. If you are uncertain whether your child's prescription drug contains an MAOI, consult a health professional before giving this product."

(iii) For oral nasal decongestant products labeled for both adults and children under 12 years of age. The labeling of the product contains the warnings identified in paragraph (c)(3)(i) of this section.

(2) Topical decongestants—(i) For products containing any topical decongestant identified in § 341.20(b) when labeled for adults.

(A) "Do not exceed recommended dosage." [sentence in boldface type]

(B) "This product may cause temporary discomfort such as burning, stinging, sneezing, or an increase in nasal discharge."

(C) "The use of this container by more than one person may spread infection."

(ii) For products containing ephedrine, ephedrine hydrochloride, ephedrine sulfate, naphazoline hydrochloride, oxymetazoline hydrochloride, phenylephrine hydrochloride, or xylometazoline hydrochloride identified in § 341.20(b)(2), (b)(3), (b)(4), (b)(6), (b)(7), and (b)(8) when used as nasal sprays, drops, or jellies and when labeled for adults.

(A) "Do not use this product for more than 3 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen. If symptoms persist, consult a doctor."

(B) "Do not use this product if you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland unless directed by a doctor."

(iii) For products containing ephedrine, ephedrine hydrochloride, ephedrine sulfate, naphazoline hydrochloride, oxymetazoline hydrochloride, phenylephrine hydrochloride, or xylometazoline hydrochloride identified in § 341.20(b)(7), when labeled for children under 12 years of age when used in an inhalant dosage form.

(iv) For products containing naphazoline hydrochloride identified in § 341.20(b)(6) at a concentration of 0.05 percent. "Do not use this product in children under 12 years of age because it may cause sedation if swallowed."

(v) For products containing propylhexedrine identified in § 341.20(b)(9) when used in an inhalant dosage form and when labeled for adults. "Do not use this product for more than 3 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen. If symptoms persist, consult a doctor."

(vi) For products containing any topical nasal decongestant identified in § 341.20(b) when labeled for children under 12 years of age. The labeling of the product contains the warnings identified in paragraph (c)(2)(i) of this section.

(vii) [Reserved]

(viii) For products containing ephedrine, ephedrine hydrochloride, ephedrine sulfate, naphazoline hydrochloride, oxymetazoline hydrochloride, phenylephrine hydrochloride, or xylometazoline hydrochloride identified in § 341.20(b)(8) when used in an inhalant dosage form and when labeled for children under 12 years of age. The labeling contains the warnings identified in paragraph (c)(2)(i) of this section.
oxymetazoline hydrochloride, phenylephrine hydrochloride, or xylometazoline hydrochloride identified in § 341.20(b)(2), (b)(3), (b)(4), (b)(6), (b)(7), (b)(8), and (b)(10) when used as nasal sprays, drops, or jellies and when labeled for children under 12 years of age. (A) “Do not use this product for more than 3 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen. If symptoms persist, consult a doctor.”

(B) “Do not use this product in a child who has heart disease, high blood pressure, thyroid disease, or diabetes unless directed by a doctor.”

(ix) For products containing propylhexedrine identified in § 341.20(b)(9) when used in an inhalant dosage form and when labeled for children under 12 years of age. “Do not use this product for more than 3 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen. If symptoms persist, consult a doctor.”

(x) For topical nasal decongestant products labeled for both adults and for children under 12 years of age. The labeling of the product contains the applicable warnings identified in paragraphs (c)(2)(i), (c)(2)(ii), (c)(2)(iii), and (c)(2)(v) of this section.

(d) Directions. The labeling of the product contains the following information under the heading “Directions”:

(i) Oral nasal decongestants—(i) For products containing phenylephrine hydrochloride identified in § 341.20(a)(1). Adults and children 12 years of age and over: 10 milligrams every 4 hours not to exceed 60 milligrams in 24 hours. Children 6 to under 12 years of age: 5 milligrams every 4 hours not to exceed 30 milligrams in 24 hours. Children 2 to under 6 years of age: 2.5 milligrams every 4 hours not to exceed 15 milligrams in 24 hours. Children under 2 years of age: consult a doctor.

(ii) For products containing pseudoephedrine hydrochloride or pseudoephedrine sulfate identified in § 341.20(a)(2) and (a)(3). Adults and children 12 years of age and over: 60 milligrams every 4 to 6 hours not to exceed 240 milligrams in 24 hours. Children 6 to under 12 years of age: 30 milligrams every 4 to 6 hours not to exceed 120 milligrams in 24 hours. Children 2 to under 6 years of age: 15 milligrams every 4 to 6 hours not to exceed 60 milligrams in 24 hours. Children under 2 years of age: consult a doctor.

(ii) For products containing ephedrine, ephedrine hydrochloride, or ephedrine sulfate identified in § 341.20(b)(2), (b)(3), and (b)(4)—(A) Nasal drops or sprays—For a 0.5-percent aqueous solution. Adults and children 12 years of age and over: 2 or 3 drops or sprays in each nostril not more often than every 4 hours. Children 6 to under 12 years of age (with adult supervision): 1 or 2 drops or sprays in each nostril not more often than every 4 hours. Children under 6 years of age: consult a doctor.

(B) Nasal jelly—for a 0.5-percent water-based jelly. Adults and children 6 to under 12 years of age (with adult supervision): place a small amount in each nostril and inhale well back into the nasal passages. Use not more often than every 4 hours.

(iii) For products containing naphazoline hydrochloride identified in § 341.20(b)(6)—(A) Nasal drops or sprays—(1) For a 0.05-percent aqueous solution. Adults and children 12 years of age and over: 1 or 2 drops or sprays in each nostril not more often than every 6 hours. Do not give to children under 12 years of age unless directed by a doctor.

(2) For a 0.025-percent aqueous solution. Children 6 to under 12 years of age (with adult supervision): 1 or 2 drops or sprays in each nostril not more often than every 6 hours. Children under 6 years of age: consult a doctor.

(B) Nasal jelly—(1) For a 0.05-percent water-based jelly. Adults and children 12 years of age and over: place a small amount in each nostril and inhale well back into the nasal passages. Use not more often than every 6 hours. Do not give to children under 12 years of age unless directed by a doctor.

(2) For a 0.025-percent water-based jelly. Children 6 to under 12 years of age (with adult supervision): place a small amount in each nostril and inhale well back into the nasal passages. Use not more often than every 6 hours. Children under 6 years of age: consult a doctor.
(iv) For products containing oxymetazoline hydrochloride identified in §341.20(b)(7)—(A) Nasal drops or sprays—
(1) For a 0.05-percent aqueous solution. Adults and children 6 to under 12 years of age (with adult supervision): 2 or 3 drops or sprays in each nostril not more often than every 10 to 12 hours. Do not exceed 2 doses in any 24-hour period. Children under 6 years of age: consult a doctor.

(2) A 0.025-percent aqueous solution in a container having either a calibrated dropper or a metered-dose spray that delivers no more than 0.027 milligrams of oxymetazoline per three drops or three sprays. Children 2 to under 6 years of age (with adult supervision): 2 or 3 drops or sprays in each nostril not more often than every 4 hours. Use only recommended amount. Do not exceed 2 doses in any 24-hour period. Children under 2 years of age: consult a doctor.

(B) Nasal jelly—(1) For a 0.125-percent aqueous solution in a container having either a calibrated dropper or a metered-dose spray that delivers no more than 0.135 milligrams of phenylephrine per three drops or three sprays. Children 2 to under 6 years of age (with adult supervision): 2 or 3 drops or sprays in each nostril not more often than every 4 hours. Use only recommended amount. Do not exceed 2 doses in any 24-hour period. Children under 2 years of age: consult a doctor.

(2) For a 0.25-percent aqueous solution. Adults and children 6 to under 12 years of age (with adult supervision): place a small amount in each nostril and inhale well back into the nasal passages. Use not more often than every 4 hours. Do not exceed 2 doses in any 24-hour period. Children under 6 years of age: consult a doctor.

(3) For a 0.5-percent aqueous solution. Adults and children 6 to under 12 years of age (with adult supervision): place a small amount in each nostril and inhale well back into the nasal passages. Use not more often than every 4 hours. Children under 6 years of age: consult a doctor.

(v) For products containing phenylephrine hydrochloride identified in §341.20(b)(8)—(A) Nasal drops or sprays—
(1) For a 1-percent aqueous solution. Adults and children 6 to under 12 years of age: place a small amount in each nostril and inhale well back into the nasal passages. Use not more often than every 10 to 12 hours. Do not give to children under 12 years of age unless directed by a doctor.

(2) A 0.5-percent aqueous solution. Adults and children 6 to under 12 years of age: place a small amount in each nostril and inhale well back into the nasal passages. Use not more often than every 4 hours. Do not exceed 2 doses in any 24-hour period. Children under 6 years of age: consult a doctor.

(B) Nasal jelly—(1) For a 0.1-percent aqueous solution in a container having either a calibrated dropper or a metered-dose spray that delivers no more than 0.054 milligrams of phenylephrine per three drops or three sprays. Children 2 to under 6 years of age (with adult supervision): 2 or 3 drops or sprays in each nostril not more often than every 4 hours. Use only recommended amount. Do not exceed 2 doses in any 24-hour period. Children under 2 years of age: consult a doctor.

(2) For a 0.25-percent aqueous solution. Adults and children 6 to under 12 years of age (with adult supervision): place a small amount in each nostril and inhale well back into the nasal passages. Use not more often than every 4 hours. Do not exceed 2 doses in any 24-hour period. Children under 6 years of age: consult a doctor.

(3) For a 0.5-percent aqueous solution. Adults and children 6 to under 12 years of age: place a small amount in each nostril and inhale well back into the nasal passages. Use not more often than every 4 hours. Children under 6 years of age: consult a doctor.

(vi) For products containing propylhexedrine identified in §341.20(b)(9) when used in an inhalant dosage form.

(B) Nasal jelly—(1) For a 0.1-percent aqueous solution. Adults and children 6 to under 12 years of age (with adult supervision): place a small amount in each nostril and inhale well back into the nasal passages. Use not more often than every 2 hours. Children under 6 years of age: consult a doctor.

(B) Nasal jelly—(1) For a 0.25-percent aqueous solution. Adults and children 6 to under 12 years of age (with adult supervision): place a small amount in each nostril and inhale well back into the nasal passages. Use not more often than every 2 hours. Children under 6 years of age: consult a doctor.

(B) Nasal jelly—(1) For a 0.5-percent aqueous solution. Adults and children 6 to under 12 years of age: place a small amount in each nostril and inhale well back into the nasal passages. Use not more often than every 2 hours. Children under 6 years of age: consult a doctor.

(vii) For products containing xylometazoline hydrochloride identified in §341.20(b)(10)—(A) Nasal drops or sprays—
(1) For a 0.1-percent aqueous solution. Adults and children 6 to under 12 years of age: place a small amount in each nostril and inhale well back into the nasal passages. Use not more often than every 8 to 10 hours. Do not exceed 2 doses in any 24-hour period. Children under 6 years of age: consult a doctor.

(2) A 0.05-percent aqueous solution in a container having either a calibrated dropper or a metered-dose spray that delivers no more than 0.027 milligrams of
§ 341.90 Professional labeling.

The labeling of the product provided to health professionals (but not to the general public) may contain the following additional dosage information for products containing the active ingredients identified below:

(a) For products containing ephedrine, ephedrine hydrochloride, ephedrine sulfate, or rauwolfae hydrochloride identified in §341.16(a), (b), (c), and (f). Children 6 to under 12 years of age: oral dosage is 6.25 to 12.5 milligrams every 4 hours, not to exceed 75 milligrams in 24 hours. Children 2 to under 6 years of age: oral dosage is 0.3 to 0.5 milligram per kilogram of body weight every 4 hours, not to exceed 2 milligrams per kilogram of body weight in 24 hours.

(b) For products containing chlorpheniramine hydrochloride identified in §341.14(a)(1). Children 2 to under 6 years of age: oral dosage is 12.5 milligrams every 6 to 8 hours, not to exceed 50 milligrams in 24 hours.

(c) For products containing codeine ingredients identified in §341.14(a)(2).

1. Children 2 to under 6 years of age: Oral dosage is 1 milligram per kilogram body weight per day administered in four equal divided doses. The average body weight for each age may also be used to determine dosage as follows: For children 2 years of age (average body weight, 12 kilograms), the oral dosage is 3 milligrams every 4 to 6 hours, not to exceed 12 milligrams in 24 hours; for children 3 years of age (average body weight, 14 kilograms), the oral dosage is 3.5 milligrams every 4 to 6 hours, not to exceed 14 milligrams in 24 hours; for children 4 years of age (average body weight, 16 kilograms), the oral dosage is 4 milligrams every 4 to 6 hours, not to exceed 16 milligrams in 24 hours; for children 5 years of age (average body weight, 18 kilograms), the oral dosage is 4.5 milligrams every 4 to 6 hours, not to exceed 18 milligrams in 24 hours. The manufacturer must relate these dosages for its specific product dosages for its specific product to the use of the calibrated measuring device discussed in paragraph (c)(3) of this section. If age is used to determine the dose, the directions must include instructions to reduce the dose for low-weight children.

2. Parents should be instructed to obtain and use a calibrated measuring device for administering the drug to the child, to use extreme care in measuring the dosage, and not exceed the recommended daily dosage.

3. A dispensing device (such as a dropper calibrated for age or weight) should be dispensed along with the product when it is intended for use in children 2 to under 6 years of age to prevent possible overdose due to improper measuring of the dose.

4. Codeine is not recommended for use in children under 2 years of age. Children under 2 years may be more susceptible to the respiratory depressant effects of codeine, including respiratory arrest, coma, and death.
(d) The following labeling indication may be used for products containing guaifenesin identified in §341.18 when used as a single ingredient product. “Helps loosen phlegm and thin bronchial secretions in patients with stable chronic bronchitis.”

(e) For products containing brompheniramine maleate identified in §341.12(a). Children 2 to under 6 years of age: oral dosage is 1 milligram every 4 to 6 hours, not to exceed 6 milligrams in 24 hours.

(f) For products containing chlorcyclizine hydrochloride identified in §341.12(b). Children 6 to under 12 years of age: oral dosage is 12.5 milligrams every 6 to 8 hours, not to exceed 37.5 milligrams in 24 hours. Children 2 to under 6 years of age: oral dosage is 6.25 milligrams every 6 to 8 hours, not to exceed 18.75 milligrams in 24 hours.

(g) For products containing chlorpheniramine maleate identified in §341.12(c). Children 2 to under 6 years of age: oral dosage is 1 milligram every 4 to 6 hours, not to exceed 6 milligrams in 24 hours.

(h) For products containing dexchlorpheniramine maleate identified in §341.12(d). Children 2 to under 6 years of age: oral dosage is 0.5 milligram every 4 to 6 hours, not to exceed 3 milligrams in 24 hours.

(i) For products containing dexchlorpheniramine maleate identified in §341.12(e). Children 2 to under 6 years of age: oral dosage is 0.5 milligram every 4 to 6 hours, not to exceed 3 milligrams in 24 hours.

(j) For products containing diphenhydramine citrate identified in §341.12(f). Children 2 to under 6 years of age: oral dosage is 9.5 milligrams every 4 to 6 hours, not to exceed 57 milligrams in 24 hours.

(k) For products containing diphenhydramine hydrochloride identified in §341.12(g). Children 2 to under 6 years of age: oral dosage is 6.25 milligrams every 4 to 6 hours, not to exceed 37.5 mg in 24 hours.

(l) For products containing doxylamine succinate identified in §341.12(h). Children 2 to under 6 years of age: oral dosage is 1.9 to 3.125 milligrams every 4 to 6 hours, not to exceed 18.75 milligrams in 24 hours.

(m) For products containing phenindamine tartrate identified in §341.12(i). Children 2 to under 6 years of age: oral dosage is 6.25 milligrams every 4 to 6 hours, not to exceed 37.5 milligrams in 24 hours.

(n) For products containing pheniramine maleate identified in §341.12(j). Children 2 to under 6 years of age: oral dosage is 3.125 to 6.25 milligrams every 4 to 6 hours, not to exceed 37.5 milligrams in 24 hours.

(o) For products containing pyrilamine maleate identified in §341.12(k). Children 2 to under 6 years of age: oral dosage is 1.9 to 3.125 milligrams every 4 to 6 hours, not to exceed 18.75 milligrams in 24 hours.

(q) For products containing triprolidine hydrochloride identified in §341.12(m). Children 4 to under 6 years of age: oral dosage is 9.5 milligrams every 4 hours, not to exceed 57 milligrams in 24 hours. Children 2 to under 6 years of age: oral dosage is 6.25 milligrams every 4 to 6 hours, not to exceed 2.5 milligrams in 24 hours. Infants 4 months to under 2 years of age: oral dosage is 0.313 milligram every 4 to 6 hours, not to exceed 1.252 milligrams in 24 hours.

(r) For products containing diphenhydramine citrate identified in §341.14(a)(5). Children 2 to under 6 years of age: oral dosage is 9.5 milligrams every 4 to 6 hours, not to exceed 37.5 milligrams in 24 hours.

(s) For products containing diphenhydramine hydrochloride identified in §341.14(a)(6). Children 2 to under 6 years of age: oral dosage is 6.25 milligrams every 4 hours, not to exceed 37.5 milligrams in 24 hours.