

§ 341.80

21 CFR Ch. I (4-1-07 Edition)

(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”:

(1) “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 a fever, rash, or persistent headache, consult a doctor.”

(2) *For expectorant drug products labeled for adults or for adults and children under 12 years of age.* “Do not take this product for persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema, or where cough is accompanied by excessive phlegm (mucus) unless directed by a doctor.”

(3) *For expectorant drug products 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.”

(d) *Directions.* The labeling of the product contains the following information under the heading “Directions” for products containing guaifenesin identified in § 341.18: Adults and children 12 years of age and over: oral dosage is 200 to 400 milligrams every 4 hours not to exceed 2,400 milligrams in 24 hours. Children 6 to under 12 years of age: oral dosage is 100 to 200 milligrams every 4 hours not to exceed 1,200 milligrams in 24 hours. Children 2 to under 6 years of age: oral dosage is 50 to 100 milligrams every 4 hours not to exceed

600 milligrams in 24 hours. 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.

[54 FR 8509, Feb. 28, 1989, as amended at 57 FR 29177, June 30, 1992]

§ 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 nonmisleading 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, pseudoephedrine sulfate, or phenylephrine bitartrate identified in § 341.20 (a)(1) through (a)(4) when labeled for adults.* (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 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 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 do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.”

(ii) *For products containing phenylephrine hydrochloride, pseudoephedrine hydrochloride, pseudoephedrine sulfate, or phenylephrine bitartrate identified in § 341.20 (a)(1) through (a)(4) 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 use in a child who is 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 do not know if your child’s prescription drug contains an MAOI, ask a doctor or pharmacist 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)(1)(i) of this section.

(2) *Topical nasal decongestants*—(i) *For products containing any topical nasal 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 levmetamfetamine identified in § 341.20(b)(1) when used in an inhalant dosage form and when labeled for adults.* “Do not use this product for more than 7 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen. If symptoms persist, ask 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)(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 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.”

(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) *For products containing levmetamfetamine identified in § 341.20(b)(1) 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 7 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen. If symptoms persist, ask a doctor.”

(viii) *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), (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”:

(1) *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.

(iii) *For products containing phenylephrine bitartrate identified in § 341.20(a)(4).* Include information on the number of dosage units and the quantity of water the dosage units are to be dissolved in prior to administration as shown in the following table:

Age ¹	Dose ¹
Adults and children 12 years of age and over	15.6 milligrams every 4 hours not to exceed 62.4 milligrams in 24 hours
Children 6 to under 12 years of age	7.8 milligrams every 4 hours not to exceed 31.2 milligrams in 24 hours
Children under 6 years of age	Ask a doctor

¹Headings are not required to appear in the product's labeling

(2) *Topical nasal decongestants*—(i) *For products containing levmetamfetamine identified in § 341.20(b)(1) when used in an inhalant dosage form.* The product delivers in each 800 milliliters of air 0.04 to 0.150 milligrams of levmetamfetamine. Adults: 2 inhalations in each nostril not more often than every 2 hours. Children 6 to under 12 years of age (with adult supervision): 1 inhalation in each nostril not more often than every 2 hours. Children under 6 years of age: ask a doctor.

(ii) *For products containing ephedrine, ephedrine hydrochloride, or ephedrine sulfate identified in § 341.20(b) (2), (3), and (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 10 to 12 hours. Use only recommended amount. Do not exceed 2 doses in any 24-hour period. [previous two sentences in boldface type] Children under 2 years of age: consult a doctor.

(B) *Nasal jelly—For a 0.05-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 10 to 12 hours. Do not exceed 2 doses in any 24-hour period. 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 12 years of age and

over: 2 or 3 drops or sprays in each nostril not more often than every 4 hours. Do not give to children under 12 years of age unless directed by a doctor.

(2) *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. Do not give to children under 12 years of age unless directed by a doctor.

(3) *For a 0.25-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 4 hours. Children under 6 years of age: consult a doctor.

(4) *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. [previous sentence in boldface type] Children under 2 years of age: consult a doctor.

(B) *Nasal jelly—(1) For a 1-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 4 hours. Do not give to children under 12 years of age unless directed by a doctor.

(2) *For a 0.5-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 4 hours. Do not give to children under 12 years of age unless directed by a doctor.

(3) *For a 0.25-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. 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.* The product delivers in each 800 milliliters of air 0.40 to 0.50 milligrams of propylhexedrine. Adults and children 6

to under 12 years of age (with adult supervision): 2 inhalations in each nostril 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 12 years of age and over: 2 or 3 drops or sprays in each nostril not more often than every 8 to 10 hours. Do not give to children under 12 years of age unless directed by 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 0.054 milligrams of xylometazoline per three drops or three sprays.* 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 8 to 10 hours. 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 8 to 10 hours. Use only recommended amount. Do not exceed 3 doses in any 24-hour period. [previous two sentences in boldface type] Children under 2 years of age: consult a doctor.

(B) *Nasal jelly—(1) For a 0.1-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 8 to 10 hours. Do not give to children under 12 years of age unless directed by a doctor.

(2) *For a 0.05-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 8 to 10 hours. Children under 6 years of age: consult a doctor.

(viii) *Other required statements—For products containing levmetamfetamine or propylhexedrine identified in § 341.20(b)(1) or (b)(9) when used in an inhalant dosage form.* (A) “This inhaler is effective for a minimum of 3 months after first use.”

(B) “Keep inhaler tightly closed.”

[59 FR 43409, Aug. 23, 1994, as amended at 63 FR 40650, July 30, 1998; 64 FR 13295, Mar. 17, 1999; 65 FR 8, Jan. 3, 2000; 71 FR 43362, Aug. 1, 2006]

EFFECTIVE DATE NOTE: At 70 FR 58977, Oct. 11, 2005, § 341.80 was amended by removing paragraph (b)(1)(iii), effective Apr. 11, 2007.

§ 341.85 Labeling of permitted combinations of active ingredients.

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) *Statement of identity.* For a combination drug product that has an established name, the labeling of the product states the established name of the combination drug product, followed by the statement of identity for each ingredient in the combination, as established in the statement of identity sections of the applicable OTC drug monographs. If there is no established name, the labeling of the product states the statement of identity for each ingredient in the combination, as established in the statement of identity sections of the applicable OTC drug monographs, unless otherwise stated in this paragraph (a).

(1) *For permitted combinations identified in § 341.40(a), (c), (f), (g), (l), (m), (n), (o), (q), and (r) containing an analgesic-antipyretic active ingredient.* The analgesic-antipyretic component of the product shall be identified as a “pain reliever” or “analgesic (pain reliever).” If the product is also labeled to relieve fever, then the analgesic-antipyretic component is identified as a “pain reliever-fever reducer” or “analgesic (pain reliever)-antipyretic (fever reducer).”

(2) [Reserved]

(b) *Indications.* The labeling of the product states, under the heading “Uses,” the indication(s) for each ingredient in the combination, as established in the indications sections of the applicable OTC drug monographs, unless otherwise stated in this paragraph (b). Other truthful and nonmisleading statements, describing only the indications for use that have been established

and listed in the applicable OTC drug monographs or 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 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) *For permitted combinations containing an analgesic-antipyretic active ingredient identified in § 341.40(a), (c), (f), (g), (l), (m), (n), (o), (q), and (r) when labeled for relief of general cough-cold symptoms and/or the common cold.* (i) The labeling for the analgesic-antipyretic ingredients states “[bullet] temporarily relieves [bullet] minor aches and pains [bullet] headache” and “[bullet] temporarily reduces fever”.

(ii) The labeling for the cough-cold ingredient(s) may follow a separate bullet(s) or may be combined with the relieves part of the indication in paragraph (b)(1)(i) of this section.

(2) *For permitted combinations containing an analgesic-antipyretic active ingredient identified in § 341.40 (a), (c), (f), (g), (m), (q), and (r) when labeled for relief of hay fever/allergic rhinitis and/or nasal congestion symptoms.* (i) The labeling for the analgesic-antipyretic ingredients states “[bullet] temporarily relieves [bullet] minor aches and pains [bullet] headache”.

(ii) The indication(s) for the cough-cold ingredient(s) consists of the labeling for antihistamines in § 341.72(b)(1) or (b)(2) and/or nasal decongestants in § 341.80(b)(1)(ii) and/or (b)(1)(iii), as appropriate, and the labeling for any other cough-cold ingredient present in the combination. This labeling may follow a separate bullet(s) or may be combined with the indication in paragraph (b)(2)(i) of this section.

(3) *For permitted combinations containing an oral analgesic-antipyretic active ingredient identified in § 341.40 (a), (c), (f), (g), (m), (q), and (r) when labeled for relief of general cough-cold symptoms and/or the common cold and for relief of hay fever/allergic rhinitis and/or nasal congestion symptoms.* The labeling states both indications in paragraphs (b)(1) and (b)(2) of this section.