§ 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)”).

(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.”

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

[54 FR 5099, Feb. 28, 1989, as amended at 57 FR 29177, June 30, 1992]
(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 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 naproxen sodium identified in §341.20(b)(9) when used in an oral dosage form and when labeled for children. “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.”

(v) For products containing propylhexedrine identified in §341.20(b)(9) when used in an oral dosage form and when labeled for adults. “Do not use this product in children under 12 years of age unless directed by a doctor.”

(vi) For products containing any topical nasal decongestant identified in §341.20(b) when used in an inhalant dosage form and when labeled for children. “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, consult a doctor.”

(vii) For products containing levmetamfetamine identified in §341.20(b)(1) when used in a child 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, consult 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)(9), 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 7 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. “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, consult a doctor.”

(x) For products containing any topical nasal decongestant identified in §341.20(b) 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, consult a doctor.”
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:

<table>
<thead>
<tr>
<th>Age 1</th>
<th>Dose 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults and children 12 years of age and over</td>
<td>15.6 milligrams every 4 hours not to exceed 62.4 milligrams in 24 hours</td>
</tr>
<tr>
<td>Children 6 to under 12 years of age</td>
<td>7.8 milligrams every 4 hours not to exceed 31.2 milligrams in 24 hours</td>
</tr>
<tr>
<td>Children under 6 years of age</td>
<td>Ask a doctor</td>
</tr>
</tbody>
</table>

(2) Topical nasal decongestants—(1) 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: 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.

(1) Headings are not required to appear in the product’s labeling.
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. Do not give to children under 12 years of age unless directed by 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. 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 0.025-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 0.05-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 4 hours. Chil- dren 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. Children under 2 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.

(B) Nasal jelly—(1) 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. 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): 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.

(B) Nasal jelly—(1) 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.

(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. Children under 2 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 drop-per 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. 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)(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.” 

§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