

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.”

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§ 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), as appropriate, and the labeling for any other cough-cold 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.

(4) *For permitted combinations containing an oral anesthetic-analgesic active ingredient identified in § 341.40(k), (s), (t), (z), (aa), and (bb).* The labeling for

the anesthetic-analgesic ingredients in part 356 of this chapter should be used.

(5) *For permitted combinations containing camphor, menthol, and eucalyptus oil identified in § 341.40(u).* The labeling for antitussive ingredients in § 341.74(b) should be used.

(6) *For permitted combinations containing levmetamfetamine with aromatics identified in § 341.40(v).* The labeling for nasal decongestant ingredients in § 341.80(b) should be used.

(7) *Other allowable statements.* In addition to the required information identified in paragraph (b) of this section, the labeling of the combination drug product may contain any of the “other allowable statements” (if any), that are identified in the applicable OTC drug monographs, provided such statements are neither placed in direct conjunction with information required to appear in the labeling nor occupy labeling space with greater prominence or conspicuousness than the required information.

(c) *Warnings.* The labeling of the product states, under the heading “Warnings,” the warning(s) for each ingredient in the combination, as established in the warnings sections of the applicable OTC drug monographs, unless otherwise stated in paragraph (c) of this section.

(1) *For permitted combinations containing an antitussive and an analgesic-antipyretic identified in § 341.40(f), (g), (l), and (m).* The labeling states the following warnings:

(i) *For products labeled only for adults.* The following warning should be used instead of the warnings in § 341.74(c)(1) and part 343 of this chapter: “Stop use and ask a doctor if [in bold type] [bullet] pain or cough gets worse or lasts more than 7 days [bullet] fever gets worse or lasts more than 3 days [bullet] redness or swelling is present [bullet] new symptoms occur [bullet] cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.”

(ii) *For products labeled only for children under 12 years of age.* The following warning should be used instead of the warnings in § 341.74(c)(3) and part 343 of this chapter: “Stop use and ask a doctor if [in bold type] [bullet] pain or cough gets worse or lasts more than 5

days [bullet] fever gets worse or lasts more than 3 days [bullet] redness or swelling is present [bullet] new symptoms occur [bullet] cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.”

(iii) *For products labeled for both adults and for children under 12 years of age.* The following warning should be used instead of the warnings in §341.74(c)(2) and part 343 of this chapter: “Stop use and ask a doctor if [in bold type] [bullet] pain or cough gets worse or lasts more than 5 days (children) or 7 days (adults) [bullet] fever gets worse or lasts more than 3 days [bullet] redness or swelling is present [bullet] new symptoms occur [bullet] cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.”

(2) *For permitted combinations containing an expectorant and an analgesic-antipyretic identified in §341.40(o).* The labeling states the following warnings:

(i) *For products labeled only for adults.* The warning in paragraph (c)(1)(i) of this section should be used instead of the warnings in §341.78(c)(3) and part 343 of this chapter.

(ii) *For products labeled only for children under 12 years of age.* The warning in paragraph (c)(1)(ii) of this section should be used instead of the warnings in §341.78(c)(3) and part 343 of this chapter.

(iii) *For products labeled for both adults and for children under 12 years of age.* The warning in paragraph (c)(1)(iii) of this section should be used instead of the warnings in §341.78(c)(3) and part 343 of this chapter.

(3) *For permitted combinations containing a nasal decongestant and an analgesic-antipyretic identified in §341.40(c), (g), (m), (n), (q), and (r).* The labeling states the following warnings:

(i) *For products labeled only for adults.* The following warning should be used instead of the warnings in §341.80(c)(1)(i)(B) and part 343 of this chapter: “Stop use and ask a doctor if [in bold type] [bullet] pain or nasal congestion gets worse or lasts more than 7 days [bullet] fever gets worse or lasts more than 3 days [bullet] redness or swelling is present [bullet] new symptoms occur”.

(ii) *For products labeled for only children under 12 years of age.* The following warning should be used instead of the warnings in §341.80(c)(1)(ii)(B) and part 343 of this chapter: “Stop use and ask a doctor if [in bold type] [bullet] pain or nasal congestion gets worse or lasts more than 5 days [bullet] fever gets worse or lasts more than 3 days [bullet] redness or swelling is present [bullet] new symptoms occur”.

(iii) *For products labeled for both adults and children under 12 years of age.* The following warning should be used instead of the warnings in §341.80(c)(1)(iii) and part 343 of this chapter: “Stop use and ask a doctor if [in bold type] [bullet] pain or nasal congestion gets worse or lasts more than 5 days (children) or 7 days (adults) [bullet] fever gets worse or lasts more than 3 days [bullet] redness or swelling is present [bullet] new symptoms occur”.

(4) *For permitted combinations containing an antihistamine combined with an oral antitussive.* The labeling states the warning “When using this product [in bold type] [bullet] may cause marked drowsiness.” The word “marked” may be deleted from the warning upon petition under the provisions of §10.30 of this chapter provided adequate data are submitted to demonstrate that the combination product does not cause a significant increase in drowsiness as compared with each active ingredient when tested alone. The petition and the data it contains will be maintained in a permanent file for public review in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

(5) *For permitted combinations containing camphor, menthol, and eucalyptus oil identified in §341.40(u).* The labeling states the warnings for topical antitussive ingredients in §341.74(c).

(6) *For permitted combinations containing levmetamphetamine with aromatics identified in §341.40(v).* The labeling states the warnings for topical nasal decongestant ingredients in §341.80(c)(2).

(d) *Directions.* The labeling of the product states, under the heading “Directions,” directions that conform to

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the directions established for each ingredient in the directions sections of the applicable OTC drug monographs, unless otherwise stated in paragraph (d) of this section. When the time intervals or age limitations for administration of the individual ingredients differ, the directions for the combination product may not exceed any maximum dosage limits established for the individual ingredients in the applicable OTC drug monograph.

(1) *For permitted combinations containing an anesthetic/analgesic and/or a demulcent in a liquid dosage form identified in § 341.40(k), (s), (t), (w), (x), (y), (z), (aa), and (bb).* The labeling states “[optional, bullet] gargle, swish around, or keep in the mouth for at least 1 minute and then swallow. Do not spit out.”

(2) *For permitted combinations containing camphor, menthol, and eucalyptus oil identified in § 341.40(u).* The labeling states the directions for topical antitussive ingredients in § 341.74(d).

(3) *For permitted combinations containing levmetamfetamine with aromatics identified in § 341.40(v).* The labeling states the directions for topical nasal decongestant ingredients in § 341.80(d)(2)(i) and (d)(2)(viii).

[67 FR 78170, Dec. 23, 2002, as amended at 70 FR 58977, Oct. 11, 2005; 71 FR 43362, Aug. 1, 2006]

§ 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 racephedrine 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 chlophedianol 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.*