

(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.

(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 levetamfetamine 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 levmetamfetamine 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 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 71 FR 43362, Aug. 1, 2006]

EFFECTIVE DATE NOTE: At 70 FR 58977, Oct. 11, 2005, §341.85 was amended by revising the headings in paragraphs (b)(2) and (b)(3) and by revising paragraph (b)(2)(ii), effective Apr. 11, 2007. For the convenience of the user, the revised text is set forth as follows:

**§341.85 Labeling of permitted combinations of active ingredients.**

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(b)(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.*

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(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