manufacturer's directions for using vaporizer or *For products formulated to be placed in the medication chamber of a hot steam vaporizer*. [bullet] place water in the vaporizer and follow manufacturer's directions for using vaporizer [bullet] place solution in the medication chamber only) [bullet] breathe in the medicated vapors [bullet] use up to three times daily or as directed by a doctor [bullet] children under 2 years of age: Ask 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.''

[52 FR 30055, Aug. 12, 1987; 52 FR 35610, Sept. 22, 1987; 53 FR 35809, Sept. 15, 1988; 55 FR 27808, July 6, 1990; 55 FR 40383, Oct. 3, 1990; 58 FR 54236, Oct. 20, 1993; 59 FR 29174, June 3, 1994; 59 FR 36051, July 15, 1994; 64 FR 13295, Mar. 17, 1999; 65 FR 8, Jan. 3, 2000; 65 FR 46867, Aug. 1, 2000; 67 FR 72559, Dec. 6, 2002]

§ 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) *Indication.* The labeling of the product states the following under the heading ''Use'': ''for temporary relief of mild symptoms of intermittent asthma: [bullet][1] wheezing [bullet] tightness of chest [bullet] shortness of breath''. Other truthful and nonmisleading statements, describing only the indication for use that has 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 Federal Food, Drug, and Cosmetic Act relating to misbranding and the prohibition in section 301(d) of the Federal Food, Drug, and Cosmetic Act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the Federal Food, Drug, and Cosmetic Act.

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

(1) The following statements shall appear after the subheading ''Do not use'' [in bold type]:

(i) ''[Bullet] unless a doctor said you have asthma''.

(ii) ''[Bullet] if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs taken 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.''

(2) The following information shall appear after the subheading ''Ask a doctor before use if you have'' [in bold type]: ''[bullet] ever been hospitalized for asthma [bullet] heart disease [bullet] high blood pressure [bullet] diabetes [bullet] thyroid disease [bullet] seizures [bullet] narrow angle glaucoma [bullet] a psychiatric or emotional condition [bullet] trouble urinating due to an enlarged prostate gland''.

(3) The following information shall appear after the subheading ''Ask a doctor or pharmacist before use if you are'' [in bold type]:

(i) ''[Bullet] taking prescription drugs for asthma, obesity, weight control, depression, or psychiatric or emotional conditions''.

(ii) ''[Bullet] taking any drug that contains phenylephrine, pseudoephedrine, ephedrine, or caffeine (such as for allergy, cough-cold, or pain)''.

(4) The following information shall appear after the subheading ''When using this product'' [in bold type]:

[1] See § 201.66(b)(4) of this chapter for the definition of ''bullet.''

(i) ''[Bullet] your blood pressure or heart rate may go up. This could increase your risk of heart attack or stroke, which may cause death.'' [in bold type]

(ii) ''[Bullet] your risk of heart attack or stroke increases if you: [Bullet] have a history of high blood pressure or heart disease [Bullet] take this product more frequently or take more than the recommended dose''. [in bold type]

(iii) ''[Bullet] avoid foods or beverages that contain caffeine''.

(iv) ''[Bullet] avoid dietary supplements containing ingredients reported or claimed to have a stimulant effect''.

(5) *For products containing ephedrine, ephedrine hydrochloride, ephedrine sulfate, or racephedrine hydrochloride identified in § 341.16(a), (b), (c), and (f).* (i) The following information shall appear after the subheading ''Asthma alert: Because asthma may be life threatening, see a doctor if you'' [in bold type]:

(A) ''[Bullet] are not better in 60 minutes''.

(B) ''[Bullet] get worse''.

(C) ''[Bullet] need more than [insert total number of dosage units that equals 150 milligrams] in 24 hours''.

(D) ''[Bullet] use more than [insert total number of dosage units that equals 100 milligrams] in 24 hours for 3 or more days a week''.

(E) ''[Bullet] have more than 2 asthma attacks in a week''.

(F) ''These may be signs that your asthma is getting worse.''

(G) ''[Bullet] This product will not give you asthma relief as quickly as an inhaled bronchodilator.''

(ii) This ''Asthma alert'' shall appear on any labeling that contains warnings and shall be the first warning statement under the heading ''Warnings''.

(6) *For products containing epinephrine, epinephrine bitartrate, or racepinephrine hydrochloride identified in § 341.16(d), (e), and (g).* (i) The following information shall appear after the subheading ''Asthma alert: Because asthma may be life threatening, see a doctor if you'' [in bold type]:

(A) ''[Bullet] are not better in 20 minutes''.

(B) ''[Bullet] get worse''.

(C) ''[Bullet] need more than 12 inhalations in 24 hours''.

(D) ''[Bullet] use more than 9 inhalations in 24 hours for 3 or more days a week''.

(E) ''[Bullet] have more than 2 asthma attacks in a week''.

(F) ''These may be signs that your asthma is getting worse.''

(ii) This ''Asthma alert'' shall appear on any labeling that contains warnings and shall be the first warning statement under the heading ''Warnings.''

(iii) *For products intended for use in a hand-held rubber bulb nebulizer.* The following statement shall also appear after the subheading ''Do not use'' along with the other information in paragraph (c)(1) of this section: ''[bullet] if product is brown in color or cloudy''.

(7) The following information shall appear after the subheading ''Stop use and ask a doctor if'' [in bold type]:

(i) ''[Bullet] your asthma is getting worse (see Asthma alert)''.

(ii) ''[Bullet] you have difficulty sleeping''.

(iii) ''[Bullet] you have a rapid heart beat''.

(iv) ''[Bullet] you have tremors, nervousness, or seizure''.

(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):* (i) ''[Bullet] do not take more than directed'' [sentence appears as first bulleted statement under ''Directions'' and in bold type]

(ii) ''[Bullet] adults and children 12 years of age and over: oral dose is 12.5 to 25 milligrams every 4 hours as needed. Do not take more than 150 milligrams in 24 hours''.

(iii) ''[Bullet] children under 12 years of age: ask 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:

(i) ''[Bullet] do not use more than directed'' [appears as first bulleted statement under ''Directions'' and in bold type].

(ii) ''[Bullet] adults and children 4 years of age and over: 1 to 3 inhalations not more often than every 3 hours. Do not use more than 12 inhalations in 24 hours. The use of this product by children should be supervised by an adult.''

(iii) ''[Bullet] children under 4 years of age: ask a doctor''.

(Collection of information requirement approved by the Office of Management and Budget under control number 0910–0237)

[51 FR 35339, Oct. 2, 1986, as amended at 52 FR 7126, Mar. 9, 1987; 52 FR 7830, Mar. 13, 1987; 53 FR 35810, Sept. 15, 1988; 58 FR 54242, Oct. 20, 1993; 61 FR 25146, May 20, 1996; 62 FR 9684, Mar. 4, 1997; 64 FR 13295, Mar. 17, 1999; 76 FR 44487, July 26, 2011]

§ 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'':

(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)