Food and Drug Administration, HHS

§ 341.72 Labeling of antihistamine 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 “antihistamine.”

(b) Indications. The labeling of the product states, under the heading “Indications,” any of the phrases listed in paragraph (b) of this section, as appropriate. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in this paragraph, 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 into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) “Temporarily” (select one of the following: “relieves,” “alleviates,” “decreases,” “reduces,” or “dries”) “runny nose and” (select one of the following: “relieves,” “alleviates,” “decreases,” or “dries”) “sneezing, itching of the nose or throat, and itchy, watery eyes due to hay fever” (which may be followed by one or both of the following: “or other upper respiratory allergies” or “(allergic rhinitis)”)

(2) “For the temporary relief of runny nose, sneezing, itching of the nose or throat, and itchy, watery eyes due to hay fever” (which may be followed by one or both of the following: “or other upper respiratory allergies” or “(allergic rhinitis)”)

(c) Warnings. The labeling of the product contains the following warnings, under the heading “Warnings”:

(1) “May cause excitability especially in children.”

(2) “Do not take this product, unless directed by a doctor, if you have a breathing problem such as emphysema or chronic bronchitis, or if you have glaucoma or difficulty in urination due to enlargement of the prostate gland.”

(3) For products containing brompheniramine maleate, chlorcyclizine hydrochloride, chlorpheniramine maleate, dexbrompheniramine maleate, dexchlorpheniramine maleate, phenindamine tartrate, pheniramine maleate, pyrilamine maleate, thonzylamine hydrochloride, or triprolidine hydrochloride identified in §341.12(a), (b), (c), (d), (e), (i), (j), (k), (l), and (m). “May cause drowsiness; alcohol, sedatives, and tranquillizers may increase the drowsiness effect. Avoid alcoholic beverages while taking this product. Do not take this product if you are taking sedatives or tranquillizers, without first consulting your doctor. Use caution when driving a motor vehicle or operating machinery.”

(4) For products containing diphenhydramine citrate, diphenhydramine hydrochloride, or doxylamine succinate identified in §341.12(f), (g), and (h). “May cause marked drowsiness; alcohol, sedatives, and tranquillizers may increase the drowsiness effect. Avoid alcoholic beverages while taking this product. Do not take this product if you are taking sedatives or tranquillizers, without first consulting your doctor. Use caution when driving a motor vehicle or operating machinery.”

(5) For products containing phenindamine tartrate identified in §341.12(i). “May cause nervousness and insomnia in some individuals.”

(6) For products that are labeled only for use by children under 12 years of age.
The labeling of the product contains only the warnings identified in paragraphs (c)(1) and (c)(5) of this section as well as the following:

(i) “Do not give this product to children who have a breathing problem such as chronic bronchitis, or who have glaucoma, without first consulting the child’s doctor.”

(ii) For products containing brompheniramine maleate, chlorpheniramine maleate, dexbrompheniramine maleate, phenindamine tartrate, pheniramine maleate, pyrilamine maleate, thonzylamine hydrochloride, or triprolidine hydrochloride identified in §341.12(a), (c), (d), (e), (i), (j), (k), (l), and (m). “May cause drowsiness. Sedatives and tranquilizers may increase the drowsiness effect. Do not give this product to children who are taking sedatives or tranquilizers, without first consulting the child’s doctor.”

(iii) For products containing diphenhydramine citrate, diphenhydramine hydrochloride, or doxylamine succinate identified in §341.12(f), (g), and (h). “May cause marked drowsiness. Sedatives and tranquilizers may increase the drowsiness effect. Do not give this product to children who are taking sedatives or tranquilizers, without first consulting the child’s doctor.”

(iv) For products containing diphenhydramine citrate or diphenhydramine hydrochloride identified in §341.12(f) and (g). “Do not use [bullet]1 with any other product containing diphenhydramine, even one used on skin”.

(v) For products containing diphenhydramine citrate or diphenhydramine hydrochloride identified in §341.12(f) and (g). “Do not use [bullet] with any other product containing diphenhydramine, even one used on skin”.

(d) Directions. The labeling of the product contains the following information under the heading “Directions”:

(1) For products containing brompheniramine maleate identified in §341.12(a). Adults and children 12 years of age and over: oral dosage is 4 milligrams every 4 to 6 hours, not to exceed 24 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: oral dosage is 2 milligrams every 4 to 6 hours, not to exceed 12 milligrams in 24 hours, or as directed by a doctor. Children under 6 years of age: consult a doctor.

(2) For products containing chlorcyclizine hydrochloride identified in §341.12(b). Adults and children 12 years of age and over: oral dosage is 25 milligrams every 6 to 8 hours, not to exceed 75 milligrams in 24 hours, or as directed by a doctor. Children under 12 years of age: consult a doctor.

(3) For products containing chlorpheniramine maleate identified in §341.12(c). Adults and children 12 years of age and over: oral dosage is 4 milligrams every 4 to 6 hours, not to exceed 24 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: oral dosage is 2 milligrams every 4 to 6 hours, not to exceed 12 milligrams in 24 hours, or as directed by a doctor. Children under 6 years of age: consult a doctor.

(4) For products containing dexbrompheniramine maleate identified in §341.12(d). Adults and children 12 years of age and over: oral dosage is 2 milligrams every 4 to 6 hours, not to exceed 12 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: oral dosage is 1 milligram every 4 to 6 hours, not to exceed 6 milligrams in 24 hours, or as directed by a doctor. Children under 6 years of age: consult a doctor.

(5) For products containing dexchlorpheniramine maleate identified in §341.12(e). Adults and children 12 years of age and over: oral dosage is 2 milligrams every 4 to 6 hours, not to exceed 12 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: oral dosage is 1 milligram every 4 to 6 hours, not to exceed 6 milligrams in 24 hours, or as directed by a doctor. Children under 6 years of age: consult a doctor.

(6) For products containing diphenhydramine citrate identified in §341.12(f). Adults and children 12 years of age and over: oral dosage is 38 to 76 milligrams every 4 to 6 hours, not to exceed 456 milligrams in 24 hours, or as

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1See §201.66(b)(4) of this chapter for definition of bullet symbol.
Food and Drug Administration, HHS

§ 341.74 Labeling of antitussive 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 “cough suppressant” or an “antitussive (cough suppressant).”

(b) Indications. The labeling of the product states, under the heading “Indications,” any of the phrases listed in this paragraph (b), as appropriate. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in this paragraph, may also be used, as provided in §330.11(c)(2), subject to the provisions of section 502 of