§ 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 §330.1(c)(2), 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.

1. “Temporarily” (select one of the following: “alleviates,” “calms,” “controls,” “decreases,” “quiets,” “reduces,” “relieves,” or “suppresses”) “cough due to” (select one of the following: “minor bronchial irritation” or “minor throat and bronchial irritation”) “as may occur with,” “associated with,” or “occurring with”) (select one of the following: “A cold” or “the common cold”) “or inhaled irritants.”

2. “Temporarily” (select one of the following: “alleviates,” “calms,” “controls,” “decreases,” “quiets,” “reduces,” “relieves,” or “suppresses”) “cough” (select one of the following: “as may occur with,” “associated with,” or “occurring with”) (select one of the following: “A cold” or “the common cold”) “or inhaled irritants.”

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

(i) “Cough suppressant which temporarily” (select one of the following: “Alleviates,” “controls,” “decreases,” “reduces,” “relieves,” or “suppresses”) “the impulse to cough.”

(ii) “Temporarily helps you cough less.”

(iii) “Temporarily helps to” (select one of the following: “Alleviate,” “control,” “decrease,” “reduce,” “relieve,” or “suppress”) “the cough reflex that causes coughing.”

(iv) “Temporarily” (select one of the following: “Alleviates,” “controls,” “decreases,” “reduces,” “relieves,” or “suppresses”) “the intensity of coughing.”

(v) (Select one of the following: “Alleviates,” “Controls,” “Decreases,” “Reduces,” “Relieves,” or “Suppresses”) “the intensity of coughing.”

(vi) For products containing chlophedianol hydrochloride, codeine ingredients, dextromethorphan, or dextromethorphan hydrobromide identified in §341.14(a) (1), (2), (3), and (4). “Calms the cough control center and relieves coughing.”

(vii) For products containing chlophedianol hydrochloride, dextromethorphan, dextromethorphan hydrobromide, camphor, or menthol identified in §341.14(a) (1), (2), (3), and (4). “Nonnarcotic cough suppressant for the temporary” (select one of the following: “alleviation,” “control,” “decrease,” “reduction,” “relief,” or “suppression”) “of cough.”

(b) (Select one of the following: “Alleviates,” “Controls,” “Decreases,” “Reduces,” “Relieves,” or “Suppresses”) “cough impulses without narcotics.”

(c) Warnings. The labeling of the product contains the following warnings under the heading “Warnings”: (1) For oral and topical antitussives. “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 fever, rash, or persistent headache, consult a doctor.”

(2) For oral and topical antitussives labeled only 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, or emphysema, or if cough is accompanied by excessive phlegm (mucus) unless directed by a doctor.”

(3) For oral and topical antitussives 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.”

(4) Oral antitussives—(i) For products containing codeine ingredients identified in §341.14(a)(2). “May cause or aggravate constipation.”

(ii) For products containing codeine ingredients identified in §341.14(a)(2) when labeled only for adults. “Do not take this product if you have a chronic pulmonary disease or shortness of breath unless directed by a doctor.”

(iii) For products containing codeine ingredients identified in §341.14(a)(2) when labeled only for children under 12 years of age. “Do not give this product to children who have a chronic pulmonary disease, shortness of breath, or who are taking other drugs unless directed by a doctor.”

(iv) For products containing codeine ingredients identified in §341.14(a)(2) when labeled for use in adults and children under 12 years of age. “Adults and children who have a chronic pulmonary disease or shortness of breath, or who are taking other drugs, should not take this product unless directed by a doctor.”

(v) For products containing dextromethorphan or dextromethorphan hydrobromide as identified in §341.14(a)(3) and (a)(4) when labeled for adults. “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.”

(vi) For products containing dextromethorphan or dextromethorphan hydrobromide as identified in §341.14(a)(3) and (a)(4) when labeled only for children under 12 years of age. Drug
interaction precaution. “Do not use in a child who is taking a prescription mono-
amine oxidase inhibitor (MAOI) (cer-
tain drugs for depression, psychiatric,
or emotional conditions, or Parkin-
sen’s disease), or for 2 weeks after stop-
ning the MAOI drug. If you do not
know if your child’s prescription drug
contains an MAOI ask a doctor or
pharmacist before giving this product.”

(vii) For products containing
diphenhydramine citrate or
diphenhydramine hydrochloride identified
in §341.14 (a)(5) and (a)(6). “May cause
excitability especially in children.”

(viii) For products containing
diphenhydramine citrate or
diphenhydramine hydrochloride identified
in §341.14 (a)(5) and (a)(6) when labeled
only for children under 12 years of age—
(A) “Do not give this product to chil-
dren who have a breathing problem
such as chronic bronchitis, or who have
glaucoma, without first consulting the
child’s doctor.”

(B) “May cause marked drowsiness.
Sedatives and tranquilizers may in-
crease the drowsiness effect. Do not give
this product to children who are
taking sedatives or tranquilizers, with-
out first consulting the child’s doctor.”

(C) “Do not use [bullet] with any
other product containing
diphenhydramine, even one used on
skin”.

(ix) For products containing
diphenhydramine citrate or
diphenhydramine hydrochloride identified
in §341.14 (a)(5) and (a)(6) when labeled
for use in adults and children under 12
years of age—(A) “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 uri-
nation due to enlargement of the pro-
state gland.”

(B) “May cause marked drowsiness;
alcohol, sedatives, and tranquilizers
may increase the drowsiness effect.
Avoid alcoholic beverages while taking
this product. Do not take this product
if you are taking sedatives or tranqui-
lizers, without first consulting your
doctor. Use caution when driving a
motor vehicle or operating machin-
ery.”

(C) “Do not use [bullet] with any
other product containing
diphenhydramine, even one used on
skin”.

(5) Topical antitussives—(i) For prod-
ucts containing camphor or menthol iden-
tified in §341.14 (b) (1) and (2) in a suit-
able ointment vehicle. “For external use
only. Do not take by mouth or place in
nostrils.”

(ii) For products containing camphor or menthol identified in §341.14(b) (1) and (2) for steam inhalation use. “For steam in-
halation only. Do not take by mouth.”

(iii) For any product containing cam-
phor or menthol in a suitable ointment ve-
hicle or for steam inhalation use and
meets the definition of one of the signal
words (“extremely flammable,” “flam-
nable,” “combustible”) as described in 16
CFR 1500.3(b)(10). The labeling contains
the appropriate flammability signal
word(s) followed by a colon and the
statement “Keep away from fire or
flame.”

(iv) For any product containing cam-
phor or menthol in a suitable ointment ve-
hicle and that does not contain a flamma-
bility signal word as described in 16 CFR
1500.3(b)(10). “When using this product,
do not [bullet] heat [bullet] micro-
wave [bullet] add to hot water or any
container where heating water. May
cause splattering and result in burns.”

(v) For any product containing cam-
phor or menthol in a suitable ointment ve-
hicle and that contains a flammability
signal word as described in 16 CFR
1500.3(b)(10). “When using this product,
do not [bullet] heat [bullet] microwave
[bullet] use near an open flame [bullet]
add to hot water or any container
where heating water. May cause splat-
tering and result in burns.”

(vi) For any product containing cam-
phor or menthol for steam inhalation use.
“When using this product, do not [bullet]
heat [bullet] microwave [bullet] use near
an open flame [bullet] add to hot water or any
container where heating water except when adding to cold
water only in a hot steam vaporizer.

1See §201.66(b)(4) of this chapter for defini-
tion of bullet symbol.

1For a definition of the term “bullet,” see
§201.66(b)(4) of this chapter.
May cause splattering and result in burns.’’ [Information highlighted in bold type.]

(vii) For any product formulated in a volatile vehicle. The labeling contains the following statement under the heading ‘‘Other information’’: ‘‘Close container tightly and store at room temperature away from heat.’’

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

(i) Oral antitussives—(i) For products containing chlorpheniramine hydrochloride identified in §341.14(a)(1). Adults and children 12 years of age and over: Oral dosage is 25 milligrams every 6 to 8 hours, not to exceed 100 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: Oral dosage is 12.5 milligrams every 6 to 8 hours, not to exceed 50 milligrams in 24 hours, or as directed by a doctor. Children under 6 years of age: Consult a doctor.

(ii) For products containing codeine ingredients identified in §341.14(a)(2). Adults and children 12 years of age and over: Oral dosage is 10 to 20 milligrams every 4 to 6 hours, not to exceed 120 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: Oral dosage is 5 to 10 milligrams every 4 to 6 hours, not to exceed 60 milligrams in 24 hours, or as directed by a doctor. Children under 6 years of age: Consult a doctor. A special measuring device should be used to give an accurate dose of this product to children under 6 years of age. Giving a higher dose than recommended by a doctor could result in serious side effects for your child.

(iii) For products containing dextromethorphan or dextromethorphan hydrobromide identified in §341.14(a)(3) and (4). The dosage is equivalent to dextromethorphan hydrobromide. Adults and children 12 years of age and over: Oral dosage is 10 to 20 milligrams every 4 hours or 30 milligrams every 6 to 8 hours, not to exceed 120 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: Oral dosage is 5 to 10 milligrams every 4 hours or 15 milligrams every 6 to 8 hours, not to exceed 60 milligrams in 24 hours, or as directed by a doctor. Children 2 to under 6 years of age: Oral dosage is 2.5 to 5 milligrams every 4 hours or 7.5 milligrams every 6 to 8 hours, not to exceed 30 milligrams in 24 hours, or as directed by a doctor. Children under 2 years of age: Consult a doctor.

(iv) For products containing diphenhydramine citrate identified in §341.14(a)(5). Adults and children 12 years of age and over: oral dosage is 38 milligrams every 4 hours, not to exceed 228 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: oral dosage is 19 milligrams every 4 hours, not to exceed 114 milligrams in 24 hours, or as directed by a doctor. Children under 6 years of age: Consult a doctor.

(v) For products containing diphenhydramine hydrochloride identified in §341.14(a)(6). Adults and children 12 years of age and over: oral dosage is 25 milligrams every 4 hours, not to exceed 150 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: oral dosage is 12.5 milligrams every 4 hours, not to exceed 75 milligrams in 24 hours, or as directed by a doctor. Children under 6 years of age: Consult a doctor.

(2) Topical antitussives—(i) For products containing camphor identified in §341.14(b)(1) in a suitable ointment vehicle. The product contains 4.7 to 5.3 percent camphor. ‘‘[bullet] see important warnings under ‘‘When using this product’’ [appears as the first statement under the heading ‘‘Directions’’ and is highlighted in bold type] [bullet] adults and children 2 years and older: [bullet] rub on the throat and chest in a thick layer [bullet] cover with a warm, dry cloth if desired [bullet] clothing should be loose about throat and chest to help vapors reach the nose and mouth [bullet] use up to three times daily or as directed by a doctor [bullet] children under 2 years of age: Ask a doctor.

(ii) For products containing dextromethorphan or dextromethorphan hydrobromide identified in §341.14(b)(2) in a suitable ointment vehicle. The product contains 2.6 to 2.8 percent menthol. ‘‘[bullet] see important warnings under ‘‘When using this product’’ ’’ [appears as the first statement under the heading ‘‘Directions’’ and is highlighted in bold type] [bullet] adults and children 2 years and older: [bullet] rub on the throat and chest in a thick layer [bullet] cover with a warm, dry cloth if desired [bullet] clothing should be loose about throat and chest to help vapors reach the nose and mouth [bullet] use up to three times daily or as directed by a doctor [bullet] children under 2 years of age: Ask a doctor.
§ 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) Indications. The labeling of the product states, under the heading “Indications,” the phrase listed in paragraph (b)(1) of this section. Other truthful and nonmisleading statements, describing only the indications for use that have been established and recommended by the FDA, may be included.