

AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

SOURCE: 68 FR 18881, April 17, 2003, unless otherwise noted.

Subpart A—General Provisions

§ 335.1 Scope.

(a) An over-the-counter antidiarrheal drug product in a form suitable for oral administration is generally recognized as safe and effective and is not misbranded if it meets each condition in this part and each general condition established in § 330.1 of this chapter.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§ 335.3 Definitions.

As used in this part:

(a) *Antidiarrheal*. A drug that can be shown by objective measurement to treat or control (stop) the symptoms of diarrhea.

(b) *Diarrhea*. A condition characterized by increased frequency of loose, watery stools (three or more daily) during a limited period (24 to 48 hours), usually with no identifiable cause.

(c) *Travelers' diarrhea*. A subset of diarrhea occurring in travelers that is most commonly caused by an infectious agent.

[68 FR 18881, April 17, 2003, as amended at 69 FR 26302, May 12, 2004]

Subpart B—Active Ingredients

§ 335.10 Antidiarrheal active ingredients.

The active ingredient of the product consists of any one of the following when used within the dosage limits established for each ingredient in § 335.50(d):

- (a) Bismuth subsalicylate.
- (b) Kaolin.

Subpart C—Labeling

§ 335.50 Labeling of antidiarrheal drug products.

(a) *Statement of identity*. The labeling of the product contains the established name of the drug, if any, and identifies

the product either as an “antidiarrheal” or “for diarrhea.”

(b) *Indications*. The labeling of the product states, under the heading “Use,” one or more 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 (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 products containing bismuth subsalicylate identified in § 335.10(a)*. The labeling states [select one of the following: “controls” or “relieves”] [select one or both of the following: “diarrhea” or “travelers’ diarrhea”]. If both “diarrhea” and “travelers’ diarrhea” are selected, each shall be preceded by a bullet in accordance with § 201.66(b)(4) and (d)(4) of this chapter and the heading “Uses” shall be used.

(2) *For products containing kaolin identified in § 335.10(b)*. The labeling states “helps firm stool within 24 to 48 hours”.

(3) *Additional indications*—(i) When any additional indications are used, the heading “Uses” shall be used and each listed use shall be preceded by a bullet in accord with § 201.66(b)(4) of this chapter.

(ii) In addition to the indication in paragraph (b)(1) of this section, one or both of the following may be used for products containing bismuth subsalicylate in § 335.10(a): “[bullet] reduces number of bowel movements” “[bullet] helps firm stool”.

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

(1) *For products containing any ingredient identified in § 335.10*. (i) “Do not use if you have [bullet] bloody or black stool”.

(ii) “Ask a doctor before use if you have [bullet] fever [bullet] mucus in the stool”.

(2) *For products containing bismuth subsalicylate identified in §335.10(a).* (i) The following shall appear in accordance with §201.66(c)(5)(ii) of this chapter.

(A) The Reye's syndrome warning in §201.314(h) of this chapter.

(B) "Allergy alert: Contains salicylate. Do not take if you are [bullet] allergic to salicylates (including aspirin), [bullet] taking other salicylate products".

(ii) "Do not use if you have [bullet] an ulcer [bullet] a bleeding problem".

(iii) "Ask a doctor or pharmacist before use if you are taking any drug for [bullet] anticoagulation (thinning the blood) [bullet] diabetes [bullet] gout [bullet] arthritis".

(iv) "When using this product a temporary, but harmless, darkening of the stool and/or tongue may occur".

(v) "Stop use and ask a doctor if [bullet] symptoms get worse [bullet] ringing in the ears or loss of hearing occurs [bullet] diarrhea lasts more than 2 days".

(3) *For products containing kaolin identified in §335.10(b).* (i) "Ask a doctor or pharmacist before use if you are taking any other drugs. Try to use at least 3 hours before or after taking any other drugs."

(ii) "Stop use and ask a doctor if [bullet] symptoms get worse [bullet] diarrhea lasts more than 2 days".

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

(1) *For products containing any ingredient identified in §335.10.* The labeling states "[bullet] drink plenty of clear fluids to help prevent dehydration caused by diarrhea".

(2) *For products containing bismuth subsalicylate identified in §335.10(a).* The labeling states "[bullet] adults and children 12 years and over:" 525 milligrams "every 1/2 to 1 hour, or" 1,050 milligrams "every hour as needed [bullet] do not exceed" 4,200 milligrams "in 24 hours [bullet] use until diarrhea stops but not more than 2 days [bullet] children under 12 years: ask a doctor".

(3) *For products containing kaolin identified in §335.10(b).* The labeling states "[bullet] adults and children 12 years and over:" 26.2 grams "after each loose

stool [bullet] continue to take every 6 hours until stool is firm but not more than 2 days [bullet] do not exceed" [262 grams] "in 24 hours [bullet] children under 12 years of age: ask a doctor".

(e) *Products that meet the criteria established in §201.66(d)(10) of this chapter.* The information described in §201.66(c) of this chapter shall be printed in accordance with the following specifications.

(1) The labeling shall meet the requirements of §201.66(c) of this chapter except that the information in §201.66(c)(3) of this chapter may be omitted, and the information in §201.66(c)(5) and (c)(6) of this chapter may be presented as follows:

(i) The words "Contains salicylate." may be omitted from the warning in §335.50(c)(2)(i)(B).

(ii) The subheading "When using this product" in §335.50(c)(2)(iv) may be omitted.

(iii) The words "continue to" may be omitted from the directions in §335.50(d)(3).

(2) The labeling shall be printed in accordance with the requirements of §201.66(d) of this chapter except that any requirements related to §201.66(c)(3) of this chapter and the bullet in the warning in §335.50(c)(1)(i) may be omitted.

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PART 336—ANTIEMETIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

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