

§ 335.10

(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.

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(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