PART 335—ANTIDIARRHEAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A—General Provisions

Sec. 335.1 Scope.  
335.3 Definitions.

Subpart B—Active Ingredients

§ 335.10 Antidiarrheal active ingredients.

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