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

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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.