

(2) *For products applied and left on the skin containing benzoyl peroxide identified in § 333.310(a).*

(i) The labeling states the directions in paragraph (d)(1) of this section.

(ii) The labeling states “[bullet] if going outside, apply sunscreen after using this product. If irritation or sensitivity develops, stop use of both products and ask a doctor.”

(3) *For products applied and removed from the skin containing any ingredient identified in § 333.310.* Products, such as soaps and masks, may be applied and removed and should include appropriate directions. All products containing benzoyl peroxide should include the directions in paragraph (d)(2)(ii) of this section.

(4) *Optional directions.* In addition to the required directions in paragraphs (d)(1) and (d)(2) of this section, the product may contain the following optional labeling: “*Sensitivity Test for a New User.* Apply product sparingly to one or two small affected areas during the first 3 days. If no discomfort occurs, follow the directions stated (select one of the following: ‘elsewhere on this label,’ ‘above,’ or ‘below’).”

[56 FR 41019, Aug. 16, 1991, as amended at 75 FR 9776, Mar. 4, 2010]

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.

[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.