

21 CFR Part 335

Labeling, Over-the-counter drugs.

21 CFR Part 369

Labeling, Medical devices, Over-the-counter drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR chapter I is amended as follows:

PART 310—NEW DRUGS

■ 1. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360b–360f, 360j, 361(a), 371, 374, 375, 379e; 42 U.S.C. 216, 241, 242(a), 262, 263b–263n.

■ 2. Section 310.545 is amended by adding paragraph (a)(3)(i) heading, paragraphs (a)(3)(ii) and (d)(17), and by revising paragraph (d)(1) to read as follows:

§ 310.545 Drug products containing certain active ingredients offered over-the-counter (OTC) for certain uses.

(a) * * *

(3) *Antidiarrheal drug products*—(i) *Approved as of May 7, 1991.*

* * * * *

(ii) *Approved as of April 19, 2004; April 18, 2005, for products with annual sales less than \$25,000.*

Attapulgit, activated

Bismuth subnitrate

Calcium hydroxide

Calcium polycarbophil

Charcoal (activated)

Pectin

Polycarbophil

Potassium carbonate

Rhubarb fluidextract

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(d) * * *

(1) May 7, 1991, for products subject to paragraphs (a)(1) through (a)(2)(i), (a)(3)(i), (a)(4), (a)(6)(i)(A), (a)(6)(ii)(A), (a)(7) (except as covered by paragraph (d)(3) of this section), (a)(8)(i), (a)(10)(i) through (a)(10)(iii), (a)(12)(i) through (a)(12)(iv)(A), (a)(14) through (a)(15)(i), and (a)(16) through (a)(18)(i)(A) of this section.

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(17) April 19, 2004, for products subject to paragraph (a)(3)(ii) of this section. April 18, 2005, for products with annual sales less than \$25,000.

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■ 3. Part 335 is added to read as follows:

PART 335—ANTIDIARRHEAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE**Subpart A—General Provisions**

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.

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

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.

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”] “diarrhea”.

(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