

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 revising paragraphs (a)(18)(i), (a)(18)(v), (a)(18)(vi), and (d)(1), and by adding paragraph (d)(32) to read as follows:

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

(a) * * *

(18) * * *

(i)(A) *Ingredients—Approved as of May 7, 1991.*

Allantoin (wound healing claims only)

Sulfur

Tannic acid

Zinc acetate (wound healing claims only)

(B) *Ingredients—Approved as of June 4, 2004; June 6, 2005, for products with annual sales less than \$25,000.*

Beeswax

Bismuth subnitrate

Boric acid

Cetyl alcohol

Glyceryl stearate

Isopropyl palmitate

Live yeast cell derivative

Shark liver oil

Stearyl alcohol

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(v) *Insect bite and sting drug products.*

(A) *Ingredients—Approved as of May 7, 1991.*

Alcohol

Alcohol, ethoxylated alkyl

Ammonia solution, strong

Ammonium hydroxide

Benzalkonium chloride

Camphor

Ergot fluid extract

Ferric chloride

Menthol

Peppermint oil

Phenol

Pyrimamine maleate

Sodium borate

Trolamine

Turpentine oil

Zirconium oxide

(B) *Ingredients—Approved as of June 4, 2004; June 6, 2005, for products with annual sales less than \$25,000.*

Beeswax

Bismuth subnitrate

Boric acid

Cetyl alcohol

Glyceryl stearate

Isopropyl palmitate

Live yeast cell derivative

Shark liver oil

Stearyl alcohol

(vi) *Poison ivy, poison oak, and poison sumac drug products.*

(A) *Ingredients—Approved as of May 7, 1991.*

Alcohol

Anion and cation exchange resins buffered

Benzethonium chloride

Benzocaine

Benzyl alcohol

Bismuth subnitrate

Bithionol

Boric acid

Camphor

Cetalkonium chloride

Chloral hydrate

Chlorpheniramine maleate

Creosote

Dipiperdon hydrochloride

Diphenhydramine hydrochloride

Eucalyptus oil

Ferric chloride

Glycerin

Hectorite

Hydrogen peroxide

Impatiens biflora tincture

Iron oxide

Isopropyl alcohol

Lanolin

Lead acetate

Lidocaine

Menthol

Merbromin

Mercuric chloride

Panthenol

Parethoxycaine hydrochloride

Phenol

Phenyltoloxamine dihydrogen citrate

Povidone-vinylacetate copolymers

Salicylic acid

Simethicone

Tannic acid

Topical starch

Trolamine

Turpentine oil

Zirconium oxide

Zyloxin

(B) *Ingredients—Approved as of June 4, 2004; June 6, 2005, for products with annual sales less than \$25,000.*

Beeswax

Bismuth subnitrate

Boric acid

Cetyl alcohol

Glyceryl stearate

Isopropyl palmitate

Live yeast cell derivative

Shark liver oil

Stearyl alcohol

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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), (a)(16) through (a)(18)(i)(A), (a)(18)(ii) (except as covered by paragraph (d)(22) of this section), (a)(18)(iii), (a)(18)(iv), (a)(18)(v)(A), and (a)(18)(vi)(A) of this section.

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(32) June 4, 2004, for products subject to paragraphs (a)(18)(i)(B), (a)(18)(v)(B), and (a)(18)(vi)(B) of this section. June 6, 2005, for products with annual sales less than \$25,000.

PART 347—SKIN PROTECTANT DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

■ 3. The authority citation for 21 CFR part 347 continues to read as follows:

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

■ 4. Part 347 is amended by revising the heading for subpart A to read as follows:

Subpart A—General Provisions

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■ 5. Section 347.3 is revised to read as follows:

§ 347.3 Definitions.

As used in this part:

Astringent drug product. A drug product applied to the skin or mucous membranes for a local and limited protein coagulant effect.

Lip protectant drug product. A drug product that temporarily prevents dryness and helps relieve chapping of the exposed surfaces of the lips; traditionally called “lip balm.”

Poison ivy, oak, sumac dermatitis. An allergic contact dermatitis due to exposure to plants of the genus *Rhus* (poison ivy, poison oak, poison sumac), which contain urushiol, a potent skin-sensitizer.

Skin protectant drug product. A drug product that temporarily protects injured or exposed skin or mucous membrane surfaces from harmful or annoying stimuli, and may help provide relief to such surfaces.