of biliary ducts during cholecystography.''

[54 FR 8321, Feb. 28, 1989]

Subparts D–H [Reserved]

Subpart I—Deodorant Drug Products for Internal Use

SOURCE: 55 FR 19865, May 11, 1990, unless otherwise noted.

§ 357.801 Scope.

(a) An over-the-counter deodorant drug product for internal use 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 subpart and each general condition established in § 330.1 of this chapter.

(b) References in this subpart to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§ 357.803 Definitions.

As used in this subpart:

(a) *Colostomy.* An external operative opening of the colon.

(b) *Deodorant for internal use.* An ingredient taken internally to reduce odors arising from conditions such as colostomies, ileostomies, or fecal incontinence.

(c) *Ileostomy.* An external operative opening from the ileum.

(d) *Incontinence.* An inability to retain urine or feces.

§ 357.810 Active ingredients for deodorant drug products for internal use.

The active ingredient of the product consists of either of the following when used within the dosage limits established for each ingredient in § 357.850(d):

(a) Bismuth subgallate.

(b) Chlorophyllin copper complex.

§ 357.850 Labeling of deodorant drug products for internal use.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as a ''deodorant for internal use'' or as a ''colostomy or ileostomy deodorant.''

(b) *Indications.* The labeling of the product states, under the heading ''Indications,'' any of the phrases listed in paragraph (b) of this section as appropriate. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in paragraph (b) of this section 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 subgallate identified in § 357.810(a).* ''An aid to reduce odor from a colostomy or ileostomy.''

(2) *For products containing chlorophyllin copper complex identified in § 357.810(b).* (i) ''An aid to reduce odor from a colostomy or ileostomy.''

(ii) ''An aid to reduce fecal odor due to incontinence.''

(c) *Warnings.* The labeling of the product contains the following warnings under the heading ''Warnings'': (1) *For products containing chlorophyllin copper complex identified in § 357.810(b).* (i) ''If cramps or diarrhea occurs, reduce the dosage. If symptoms persist, consult your doctor.''

(ii) The warning required by § 330.1(g) of this chapter concerning overdose is not required on products containing chlorophyllin copper complex identified in § 357.810(b).

(2) [Reserved]

(d) *Directions.* The labeling of the product contains the following information under the heading ''Directions.''

(1) *For products containing bismuth subgallate identified in § 357.810(a).* Adults and children 12 years of age and over: Oral dosage is 200 to 400 milligrams up to 4 times daily. Children under 12 years of age: consult a doctor.

(2) *For products containing chlorophyllin copper complex identified in § 357.810(b).* Adults and children 12 years of age and over: Oral dosage is 100 to 200 milligrams daily in divided doses as required. If odor is not controlled, take

up to an additional 100 milligrams daily in divided doses as required. The smallest effective dose should be used. Do not exceed 300 milligrams daily. Children under 12 years of age: consult a doctor.

PART 358—MISCELLANEOUS EXTERNAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A [Reserved]

Subpart B—Wart Remover Drug Products

Subpart C [Reserved]

Subpart D—Ingrown Toenail Relief Drug Products

Subpart E [Reserved]

Subpart F—Corn and Callus Remover Drug Products

Subpart G—Pediculicide Drug Products

Subpart H—Drug Products for the Control of Dandruff, Seborrheic Dermatitis, and Psoriasis

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

SOURCE: 55 FR 33255, Aug. 14, 1990, unless otherwise noted.

Subpart A [Reserved]

Subpart B—Wart Remover Drug Products

§ 358.101 Scope.

(a) An over-the-counter wart remover drug product in a form suitable for topical application is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this subpart and each of the general conditions established in § 330.1 of this chapter.

(b) References in this subpart to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§ 358.103 Definitions.

As used in this subpart:

(a) *Wart remover drug product.* A topical agent used for the removal of common or plantar warts.

(b) *Collodion-like vehicle.* A solution containing pyroxylin (nitrocellulose) in an appropriate nonaqueous solvent that leaves a transparent cohesive film when applied to the skin in a thin layer.

(c) *Plaster vehicle.* A fabric, plastic, or other suitable backing material in which medication is usually incorporated for topical application to the skin.

§ 358.110 Wart remover active ingredients.

The product consists of any of the following active ingredients within the specified concentration and in the dosage form established for each ingredient.

(a) Salicylic acid 12 to 40 percent in a plaster vehicle.