

## Food and Drug Administration, HHS

## § 358.103

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

Sec.

358.101 Scope.

358.103 Definitions.

358.110 Wart remover active ingredients.

358.150 Labeling of wart remover drug products.

#### Subparts C–E [Reserved]

#### Subpart F—Corn and Callus Remover Drug Products

358.501 Scope.

358.503 Definitions.

358.510 Corn and callus remover active ingredients.

358.550 Labeling of corn and callus remover drug products.

#### Subpart G—Pediculicide Drug Products

358.601 Scope.

358.603 Definition.

358.610 Pediculicide active ingredients.

358.650 Labeling of pediculicide drug products.

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

358.701 Scope.

358.703 Definitions.

358.710 Active ingredients for the control of dandruff, seborrheic dermatitis, or psoriasis.

358.720 Permitted combinations of active ingredients.

358.750 Labeling of drug products for the control of dandruff, seborrheic dermatitis, or 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.