

§ 358.501

area where the ingrown nail and the skin meet. Smooth ring down firmly. [bullet] apply enough gel product to fill the slot in the ring [bullet] place round center section of bandage strip directly over the gel-filled ring to seal the gel in place. Smooth ends of bandage strip around toes.”

(ii) “[Bullet] repeat twice daily (morning and night) for up to 7 days until discomfort is relieved or until the nail can be lifted out of the nail groove and easily trimmed”.

(2) “[Bullet] children under 12 years: ask a doctor”.

Subpart E [Reserved]

Subpart F—Corn and Callus Remover Drug Products

SOURCE: 55 FR 33261, Aug. 14, 1990, unless otherwise noted.

§ 358.501 Scope.

(a) An over-the-counter corn and callus 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.

§ 358.503 Definitions.

As used in this subpart:

(a) *Corn and callus remover drug product.* A topical agent used for the removal of corns and calluses.

(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.

21 CFR Ch. I (4–1–10 Edition)

§ 358.510 Corn and callus remover active ingredients.

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

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

(b) Salicylic acid 12 to 17.6 percent in a collodion-like vehicle.

§ 358.550 Labeling of corn and callus remover drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as a “corn and callus remover.”

(b) *Indications.* The labeling of the product states, under the heading “Indications,” the phrase listed in paragraph (b)(1) of this section and may contain the additional phrase listed in paragraph (b)(2) of this section. Other truthful and nonmisleading statements, describing only the indications for use that have been established 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 the removal of corns and calluses.”

(2) In addition to the information identified in paragraph (b)(1) of this section, the labeling of the product may contain the following statement: “Relieves pain by removing corns and calluses.”

(c) *Warnings.* The labeling of the product contains the following warnings under the heading “Warnings”:

(1) *For products containing any ingredient identified in § 358.510.* (i) “For external use only.”

(ii) “Do not use this product on irritated skin, on any area that is infected or reddened, if you are a diabetic, or if you have poor blood circulation.”

(iii) “If discomfort persists, see your doctor or podiatrist.”