(b) Salicylic acid 5 to 17 percent in a collodion-like vehicle.

(c) Salicylic acid 15 percent in a karaya gum, glycol plaster vehicle.

§ 358.150 Labeling of wart 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 ''wart remover.''

(b) *Indications.* The labeling of the product states, under the heading ''Indications,'' any of the phrases listed in paragraph (b) 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 common warts. The common wart is easily recognized by the rough 'cauliflower-like' appearance of the surface.''

(2) ''For the removal of plantar warts on the bottom of the foot. The plantar wart is recognized by its location only on the bottom of the foot, its tenderness, and the interruption of the footprint pattern.''

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

(1) *For products containing any ingredient identified in § 358.110.* (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.''

(iv) ''Do not use on moles, birthmarks, warts with hair growing from them, genital warts, or warts on the face or mucous membranes.''

(2) *For any product formulated in a flammable vehicle.* (i) The labeling should contain an appropriate flammability signal word, e.g. ''extremely flammable,'' ''flammable,'' ''combustible,'' consistent with 16 CFR 1500.3(b)(10).

(ii) ''Keep away from fire or flame.''

(3) *For any product formulated in a volatile vehicle.* ''Cap bottle tightly and store at room temperature away from heat.''

(4) *For any product formulated in a collodion-like vehicle.* (i) ''If product gets into the eye, flush with water for 15 minutes.''

(ii) ''Avoid inhaling vapors.''

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

(1) *For products containing salicylic acid identified in § 358.110(a).* ''Wash affected area.'' (Optional: ''May soak wart in warm water for 5 minutes.'') ''Dry area thoroughly.'' (If appropriate: ''Cut plaster to fit wart.'') ''Apply medicated plaster. Repeat procedure every 48 hours as needed (until wart is removed) for up to 12 weeks.''

(2) *For products containing salicylic acid identified in § 358.110(b).* ''Wash affected area.'' (Optional: ''May soak wart in warm water for 5 minutes.'') ''Dry area thoroughly. Apply'' (select one of the following, as appropriate: ''one drop'' or ''small amount'') ''at a time with'' (select one of the following, as appropriate: ''applicator'' or ''brush'') ''to sufficiently cover each wart. Let dry. Repeat this procedure once or twice daily as needed (until wart is removed) for up to 12 weeks.''

(3) *For products containing salicylic acid identified in § 358.110(c).* ''Wash affected area.'' (Optional: ''May soak wart in warm water for 5 minutes.'') ''Dry area thoroughly. Gently smooth wart surface with emery file supplied.'' (If appropriate: ''Cut plaster to fit wart.'') ''Apply a drop of warm water to the wart, keeping the surrounding skin dry. Apply medicated plaster at bedtime and leave in place for at least 8 hours. In the morning, remove plaster and discard. Repeat procedure every 24 hours as needed (until wart is removed) for up to 12 weeks.''

(e) The word ''physician'' may be substituted for the word ''doctor'' in any of the labeling statements in this section.

(f) The phrase ''or podiatrist'' may be used in addition to the word ''doctor'' in any of the labeling statements in this section when a product is labeled with the indication identified in § 358.150(b)(2).

[55 FR 33255, Aug. 14, 1990; 55 FR 37403, Sept. 11, 1990, as amended at 57 FR 44495, Sept. 28, 1992; 59 FR 60317, Nov. 23, 1994]

Subpart C [Reserved]

Subpart D—Ingrown Toenail Relief Drug Products

SOURCE: 68 FR 24348, May 7, 2003, unless otherwise noted.

§ 358.301 Scope.

(a) An over-the-counter ingrown toenail relief drug product in a form suitable for topical 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 1 of title 21 unless otherwise noted.

§ 358.303 Definitions.

As used in this subpart:

(a) *Ingrown toenail relief drug product.* A drug product applied to an ingrown toenail that relieves pain or discomfort either by softening the nail or by hardening the nail bed.

(b) *Retainer ring.* A die cut polyethylene foam pad coated on one side with medical grade acrylic pressure-sensitive adhesive. The retainer ring has slots, center-cut completely through the foam with the cut of sufficient size to allow for localization of an active ingredient in a gel vehicle to a specific target area. The retainer ring is used with adhesive bandage strips to place over the retainer ring to hold it in place.

§ 358.310 Ingrown toenail relief active ingredient.

The active ingredient of the product is sodium sulfide 1 percent in a gel vehicle. The gel vehicle is an aqueous, semisolid system with large organic molecules interpenetrated with a liquid.

§ 358.350 Labeling of ingrown toenail relief drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the product, if any, and identifies the product as an ''ingrown toenail relief product'' or as an ''ingrown toenail discomfort reliever.''

(b) *Indications.* The labeling of the product states, under the heading ''Use,'' the following: ''for temporary relief of'' [select one or both of the following: 'pain' or 'discomfort'] ''from ingrown toenails''. Other truthful and nonmisleading statements, describing only the use that has 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.

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

(1) ''For external use only'' in accord with § 201.66(c)(5)(i) of this chapter.

(2) ''Do not use [bullet][1] on open sores''.

(3) ''Ask a doctor before use if you have [bullet] diabetes [bullet] poor circulation [bullet] gout''.

(4) ''When using this product [bullet] use with a retainer ring''.

(5) ''Stop use and ask a doctor if [bullet] redness or swelling of your toe increases [bullet] discharge is present around the nail [bullet] symptoms last more than 7 days or clear up and occur again within a few days''.

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

(1) ''[Bullet] adults and children 12 years and over:''

(i) ''[Bullet] wash the affected area and dry thoroughly [bullet] place retainer ring on toe with slot over the

[1] See § 201.66(b)(4) of this chapter for definition of bullet.