§ 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 foot-print 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(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.
§ 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] on open sores”.
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:”
   1. “[Bullet] wash the affected area and dry thoroughly [bullet] place retainer ring on toe with slot over the