§ 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 active ingredient”.

(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”.

(6) “[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 active ingredient”.

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