

(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 colodion-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]

Subparts C–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) *Colodion-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.

§ 358.510 Corn and callus remover active ingredients.

The product consists of any of the following active ingredients within the