

(1) “Flammable [in bold type]: Keep away from fire or flame.”

(2) “Do not use [in bold type] in the eyes.”

(3) “Ask a doctor before use if you have [in bold type] [bullet] ear drainage or discharge [bullet] pain, irritation, or rash in the ear [bullet] had ear surgery [bullet] dizziness.”

(4) “Stop use and ask a doctor if [in bold type] irritation (too much burning) or pain occurs.”

(d) *Directions.* The labeling of the product contains the following statement under the heading “Directions”: [optional, bullet] “apply 4 to 5 drops in each affected ear.”

[65 FR 48905, Aug. 10, 2000]

PART 346—ANORECTAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A—General Provisions

Sec.

346.1 Scope.

346.3 Definitions.

Subpart B—Active Ingredients

346.10 Local anesthetic active ingredients.

346.12 Vasoconstrictor active ingredients.

346.14 Protectant active ingredients.

346.16 Analgesic, anesthetic, and antipruritic active ingredients.

346.18 Astringent active ingredients.

346.20 Keratolytic active ingredients.

346.22 Permitted combinations of anorectal active ingredients.

Subpart C—Labeling

346.50 Labeling of anorectal drug products.

346.52 Labeling of permitted combinations of anorectal active ingredients.

AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

SOURCE: 55 FR 31779, Aug. 3, 1990, unless otherwise noted.

Subpart A—General Provisions

§ 346.1 Scope.

(a) An over-the-counter anorectal drug product in a form suitable for external (topical) or intrarectal (rectal) administration is generally recognized as safe and effective and is not misbranded if it meets each condition in

this part and each general condition established in § 330.1 of this chapter.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 212 unless otherwise noted.

§ 346.3 Definitions.

As used in this part:

(a) *Analgesic, anesthetic drug.* A topically (externally) applied drug that relieves pain by depressing cutaneous sensory receptors.

(b) *Anorectal drug.* A drug that is used to relieve symptoms caused by anorectal disorders in the anal canal, perianal area, and/or the lower rectal areas.

(c) *Antipruritic drug.* A topically (externally) applied drug that relieves itching by depressing cutaneous sensory receptors.

(d) *Astringent drug.* A drug that is applied topically (externally) to the skin or mucous membranes for a local and limited protein coagulant effect.

(e) *External use.* Topical application of an anorectal drug product to the skin of the perianal area and/or the skin of the anal canal.

(f) *Intrarectal use.* Topical application of an anorectal drug product to the mucous membrane of the rectum.

(g) *Keratolytic drug.* A drug that causes desquamation (loosening) and debridement or sloughing of the surface cells of the epidermis.

(h) *Local anesthetic drug.* A drug that produces local disappearance of pain, burning, itching, irritation, and/or discomfort by reversibly blocking nerve conduction when applied to nerve tissue in appropriate concentrations.

(i) *Protectant drug.* A drug that provides a physical barrier, forming a protective coating over skin or mucous membranes.

(j) *Vasoconstrictor.* A drug that causes temporary constriction of blood vessels.

Subpart B—Active Ingredients

§ 346.10 Local anesthetic active ingredients.

The active ingredient of the product consists of any of the following when used in the concentration or within the

§ 346.12

concentration range established for each ingredient:

- (a) Benzocaine 5 to 20 percent.
- (b) Benzyl alcohol 1 to 4 percent.
- (c) Dibucaine 0.25 to 1 percent.
- (d) Dibucaine hydrochloride 0.25 to 1 percent.
- (e) Dyclonine hydrochloride 0.5 to 1 percent.
- (f) Lidocaine 2 to 5 percent.
- (g) Pramoxine hydrochloride 1 percent.
- (h) Tetracaine 0.5 to 1 percent.
- (i) Tetracaine hydrochloride 0.5 to 1 percent.

§ 346.12 Vasoconstrictor active ingredients.

The active ingredient of the product consists of any of the following when used in the concentration or within the concentration range established for each ingredient.

- (a) Ephedrine sulfate 0.1 to 1.25 percent.
- (b) Epinephrine 0.005 to 0.01 percent.
- (c) Epinephrine hydrochloride 0.005 to 0.01 percent.
- (d) Phenylephrine hydrochloride 0.25 percent.

§ 346.14 Protectant active ingredients.

(a) The following active ingredients may be used as the sole protectant active ingredient in a product if the ingredient as identified constitutes 50 percent or more by weight of the final product. In addition, the following active ingredients may be used in concentrations of less than 50 percent by weight only when used in combinations in accordance with § 346.22 (a), (b), or (n).

- (1) Aluminum hydroxide gel.
- (2) Cocoa butter.
- (3) Glycerin in a 20- to 45-percent (weight/weight) aqueous solution so that the final product contains not less than 10 and not more than 45 percent glycerin (weight/weight). Any combination product containing glycerin must contain at least this minimum amount of glycerin.
- (4) Hard fat.
- (5) Kaolin.
- (6) Lanolin.
- (7) Mineral oil.
- (8) Petrolatum.
- (9) Topical starch.

21 CFR Ch. I (4-1-08 Edition)

(10) White petrolatum.

(b) The following active ingredients may not be used as a sole protectant ingredient but may be used in combination with one, two, or three other protectant active ingredients in accordance with § 346.22 (a), (b), (n), and (o) and with the following limitations:

(1) Calamine not to exceed 25 percent by weight per dosage unit (based on the zinc oxide content of calamine).

(2) Cod liver oil, provided that the product is labeled so that the amount of the product that is used in a 24-hour period represents a quantity that provides 10,000 U.S.P. units of vitamin A and 400 U.S.P. units of cholecalciferol.

(3) Shark liver oil, provided that the product is labeled so that the amount of the product that is used in a 24-hour period represents a quantity that provides 10,000 U.S.P. units of vitamin A and 400 U.S.P. units of cholecalciferol.

(4) Zinc oxide not to exceed 25 percent by weight per dosage unit.

§ 346.16 Analgesic, anesthetic, and antipruritic active ingredients.

The active ingredient of the product consists of any of the following when used within the concentration range established for each ingredient:

- (a) Camphor 0.1 to 3 percent.
- (b) Juniper tar 1 to 5 percent.
- (c) Menthol 0.1 to 1 percent.

§ 346.18 Astringent active ingredients.

The active ingredient of the product consists of any of the following when used within the concentration range established for each ingredient:

(a) Calamine, within a concentration range of 5 to 25 percent by weight per dosage unit (based on the zinc oxide content of calamine).

(b) Witch hazel, 10 to 50 percent.

(c) Zinc oxide, within a concentration range of 5 to 25 percent by weight per dosage unit.

[55 FR 31779, Aug. 3, 1990, as amended at 59 FR 28767, June 3, 1994]

§ 346.20 Keratolytic active ingredients.

The active ingredient of the product consists of any of the following when used within the concentration range established for each ingredient:

- (a) Alcloxa 0.2 to 2 percent.
- (b) Resorcinol 1 to 3 percent.