

(b) *Aspirin capsules.* Aspirin capsules must meet the dissolution standard for aspirin capsules as contained in the United States Pharmacopeia (USP) 23 at page 132.

(c) *Aspirin delayed-release capsules and aspirin delayed-release tablets.* Aspirin delayed-release capsules and aspirin delayed-release tablets must meet the drug release standard for aspirin delayed-release capsules and aspirin delayed-release tablets as contained in USP 23 at pages 133 and 136 respectively.

(d) *Aspirin tablets.* Aspirin tablets must meet the dissolution standard for aspirin tablets as contained in USP 23 at page 134.

(e) *Aspirin, alumina, and magnesia tablets.* Aspirin in combination with alumina and magnesia in a tablet dosage form must meet the dissolution standard for aspirin, alumina, and magnesia tablets as contained in USP 23 at page 138.

(f) *Aspirin, alumina, and magnesium oxide tablets.* Aspirin in combination with alumina, and magnesium oxide in a tablet dosage form must meet the dissolution standard for aspirin, alumina, and magnesium tablets as contained in USP 23 at page 139.

(g) *Aspirin effervescent tablets for oral solution.* Aspirin effervescent tablets for oral solution must meet the dissolution standard for aspirin effervescent tablets for oral solution as contained in USP 23 at page 137.

(h) *Buffered aspirin tablets.* Buffered aspirin tablets must meet the dissolution standard for buffered aspirin tablets as contained in USP 23 at page 135.

## PART 344—TOPICAL OTIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

### Subpart A—General Provisions

Sec.

344.1 Scope.

344.3 Definitions.

### Subpart B—Active Ingredients

344.10 Topical otic active ingredient.

### Subpart C—Labeling

344.50 Labeling of topical otic drug products.

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

SOURCE: 51 FR 28660, Aug. 8, 1986, unless otherwise noted.

## Subpart A—General Provisions

### §344.1 Scope.

(a) An over-the-counter topical otic drug product in a form suitable for topical administration is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this part in addition to each of the general conditions established in §330.1.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

### §344.3 Definitions.

As used in this part:

(a) *Anhydrous glycerin.* An ingredient that may be prepared by heating glycerin U.S.P. at 150° C for 2 hours to drive off the moisture content.

(b) *Earwax removal aid.* A drug used in the external ear canal that aids in the removal of excessive earwax.

## Subpart B—Active Ingredients

### §344.10 Topical otic active ingredient.

The active ingredient of the product consists of carbamide peroxide 6.5 percent formulated in an anhydrous glycerin vehicle.

## Subpart C—Labeling

### §344.50 Labeling of topical otic 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 an “earwax removal aid.”

(b) *Indication.* The labeling of the product states, under the heading “Indication,” the following: “For occasional use as an aid to” (which may be followed by: “soften, loosen, and”) “remove excessive earwax.” Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in this paragraph (b), may also be used, as

Food and Drug Administration, HHS

§ 346.3

provided in §330.1(c)(2), subject to the provisions of section 502 of 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) "Do not use if you have ear drainage or discharge, ear pain, irritation, or rash in the ear or are dizzy; consult a doctor."

(2) "Do not use if you have an injury or perforation (hole) of the ear drum or after ear surgery unless directed by a doctor."

(3) "Do not use for more than 4 days; if excessive earwax remains after use of this product, consult a doctor."

(4) "Avoid contact with the eyes."

(d) *Directions.* The labeling of the product contains the following statement under the heading "Directions": FOR USE IN THE EAR ONLY. Adults and children over 12 years of age: tilt head sideways and place 5 to 10 drops into ear. Tip of applicator should not enter ear canal. Keep drops in ear for several minutes by keeping head tilted or placing cotton in the ear. Use twice daily for up to 4 days if needed, or as directed by a doctor. Any wax remaining after treatment may be removed by gently flushing the ear with warm water, using a soft rubber bulb ear syringe. Children under 12 years of age: consult a doctor.

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

[51 FR 28660, Aug. 8, 1986; 52 FR 7830, Mar. 13, 1987]

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 anti-pruritic 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.