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Subpart D—Testing Procedures

§ 343.90 Dissolution and drug release testing.

(a) [Reserved]

(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 Earwax removal aid active ingredient.
344.12 Ear drying aid active ingredient.

Subpart C—Labeling

344.50 Labeling of earwax removal aid drug products.
344.52 Labeling of ear drying aid 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.

(c) *Water-clogged ears.* The retention of water in the external ear canal, thereby causing discomfort and a sensation of fullness or hearing impairment.

(d) *Ear drying aid.* A drug used in the external ear canal to help dry water-clogged ears.

[51 FR 28660, Aug. 8, 1986, as amended at 65 FR 48905, Aug. 10, 2000]

Subpart B—Active Ingredients

§ 344.10 Earwax removal aid active ingredient.

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

[51 FR 28660, Aug. 8, 1986, as amended at 65 FR 48905, Aug. 10, 2000]

§ 344.12 Ear drying aid active ingredient.

The active ingredient of the product consists of isopropyl alcohol 95 percent in an anhydrous glycerin 5 percent base.

[65 FR 48905, Aug. 10, 2000]

Subpart C—Labeling

§ 344.50 Labeling of earwax removal aid 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 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.

[51 FR 28660, Aug. 8, 1986; 52 FR 7830, Mar. 13, 1987; 65 FR 48905, Aug. 10, 2000]

§ 344.52 Labeling of ear drying aid 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 ''ear drying aid.''

(b) *Indications.* The labeling of the product states, under the heading ''Use,'' the following: ''dries water in the ears'' (optional, which may be followed by: ''and relieves water-clogged ears'') (which may be followed by any or all of the following: ''after: [bullet][1] swimming [bullet] showering [bullet] bathing [bullet] washing the hair''). Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed 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.

(c) *Warnings.* The labeling of the product contains the following warnings under the heading ''Warnings'':

[1] See § 201.66(b)(4) of this chapter.

(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