

(5) *For all concentrated treatment rinse solutions, powders, and effervescent tablets.* The following statement shall appear as the first statement under directions: "Do not use before mixing with water."

(e) *Additional labeling statements for anticaries drug products.* The following statements need not appear under warnings, but are required to appear on the label of anticaries drugs products as applicable.

(1) *For all preventive treatment gels.* "This is a(n)" (select one or both of the following: "anticavity" or "fluoride") "preventive treatment gel, not a toothpaste. Read directions carefully before using."

(2) *For all stannous fluoride treatment rinse, preventive treatment gel, and dentifrice products.* "This product may produce surface staining of the teeth. Adequate toothbrushing may prevent these stains which are not harmful or permanent and may be removed by your dentist."

(f) *Optional additional labeling statements—(1) For fluoride treatment rinses and preventive treatment gels.* The following labeling statement may appear in the required boxed area designated "APPROVED USES": "The combined daily use of a fluoride preventive treatment" (select one of the following: "rinse" or "gel") "and a fluoride toothpaste can help reduce the incidence of dental cavities."

(2) *For dentifrice products containing 1,500 ppm theoretical total fluorine.* "Adults and children over 6 years of age may wish to use this extra-strength fluoride dentifrice if they reside in a nonfluoridated area or if they have a greater tendency to develop cavities."

[60 FR 52507, Oct. 6, 1995; 60 FR 57927, Nov. 24, 1995; 61 FR 51187, Oct. 7, 1996]

§ 355.55 Principal display panel of all fluoride rinse drug products.

In addition to the statement of identity required in § 355.50, the following statement shall be prominently placed on the principal display panel: "IMPORTANT: Read directions for proper use."

§ 355.60 Professional labeling.

(a) The labeling for anticaries fluoride treatment rinses identified in § 355.10(a)(3) and (c)(3) that are specially formulated so they may be swallowed (fluoride supplements) and are provided to health professionals (but not to the general public) may contain the following additional dosage information: Children 3 to under 14 years of age: As a supplement in areas where the water supply is nonfluoridated (less than 0.3 parts per million (ppm)), clean the teeth with a toothpaste and rinse with 5 milliliters (mL) of 0.02 percent or 10 mL of 0.01 percent fluoride ion rinse daily, then swallow. When the water supply contains 0.3 to 0.7 ppm fluoride ion, reduce the dose to 2.5 mL of 0.02 percent or 5 mL of 0.01 percent fluoride ion rinse daily.

(b) The labeling for products marketed to health to health professionals in package sizes larger than those specified in § 355.20 shall include the statements: "For Professional Office Use Only" and "This product is not intended for home or unsupervised consumer use."

Subpart D—Testing Procedures

§ 355.70 Testing procedures for fluoride dentifrice drug products.

(a) A fluoride dentifrice drug product shall meet the biological test requirements for animal caries reduction and one of the following tests: Enamel solubility reduction or fluoride enamel uptake. The testing procedures for these biological tests are labeled *Biological Testing Procedures for Fluoride Dentifrices*; these testing procedures are on file under Docket No. 80N-0042 in the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, and are available on request to that office.

(b) The United States Pharmacopeia fluoride dentifrice reference standards along with reference standard stability profiles (total fluoride, available fluoride ion, pH, and specific gravity) required to be used in the biological tests are available to any purchaser upon written request to the United States Pharmacopeial Convention, Inc., 1260

Twinbrook Parkway, Rockville, MD 20852.

(c) Alternative testing procedures may be used. Any proposed modification or alternative testing procedures shall be submitted as a petition in accord with §10.30 of this chapter. The petition should contain data to support the modification or data demonstrating that an alternative testing procedure provides results of equivalent accuracy. All information submitted will be subjected to the disclosure rules in part 20 of this chapter.

PART 357—MISCELLANEOUS INTERNAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A [Reserved]

Subpart B—Anthelmintic Drug Products

Sec.

- 357.101 Scope.
- 357.103 Definition.
- 357.110 Anthelmintic active ingredient.
- 357.150 Labeling of anthelmintic drug products.
- 357.152 Package inserts for anthelmintic drug products.
- 357.180 Professional labeling.

Subpart C—Cholecystokinetic Drug Products

- 357.201 Scope.
- 357.203 Definition.
- 357.210 Cholecystokinetic active ingredients.
- 357.250 Labeling of cholecystokinetic drug products.
- 357.280 Professional labeling.

Subparts D–H [Reserved]

Subpart I—Deodorant Drug Products for Internal Use

- 357.801 Scope.
- 357.803 Definitions.
- 357.810 Active ingredients for deodorant drug products for internal use.
- 357.850 Labeling of deodorant drug products for internal use.

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

Subpart A [Reserved]

Subpart B—Anthelmintic Drug Products

SOURCE: 51 FR 27759, Aug. 1, 1986, unless otherwise noted.

§357.101 Scope.

(a) An over-the-counter anthelmintic drug product in a form suitable for oral administration is generally recognized as safe and effective and is not misbranded if it meets each condition in this subpart and each general condition established in §330.1.

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

§357.103 Definition.

As used in this subpart:

Anthelmintic. An agent that is destructive to worms.

§357.110 Anthelmintic active ingredient.

The active ingredient of the product is pyrantel pamoate when used within the dosage limits established in §357.150(d)(1).

§357.150 Labeling of anthelmintic 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 a "pinworm treatment."

(b) *Indication.* The labeling of the product states, under the heading "Indication," the following: "For the treatment of pinworms." 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.