after brushing your teeth with a toothpaste. Apply the gel to your teeth and brush thoroughly. Allow the gel to remain on your teeth for 1 minute and then spit out. Do not swallow the gel. Do not eat or drink for 30 minutes after brushing. Instruct children under 12 years of age in the use of this product (to minimize swallowing). Supervise children as necessary until capable of using without supervision. Children under 6 years of age: consult a dentist or doctor.

(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 an(antacavity 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.”

21 CFR Ch. I (4–1–13 Edition)

§ 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 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 Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 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.

(60 FR 52507, Oct. 6, 1995, as amended at 68 FR 24879, May 9, 2003)

PART 357—MISCELLANEOUS INTER-INAL 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—Cholecystokininetic Drug Products

357.201 Scope.
357.203 Definition.
357.210 Cholecystokininetic active ingredients.
357.250 Labeling of cholecystokininetic drug products.
357.280 Professional labeling.

Subparts D–H [Reserved]

§ 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

313