§ 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
Subpart A [Reserved]

Subpart B—Anthelmintic Drug Products

§ 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