Food and Drug Administration, HHS

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 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—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]