

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.