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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.


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

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

Subpart A [Reserved]

Subpart B—Anthelmintic Drug Products

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Subpart C—Cholecystokinetic Drug Products

357.201 Scope.
357.203 Definition.
357.210 Cholecystokinetic active ingredients.
357.250 Labeling of cholecystokinetic drug products.
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