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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.

(c) *Warnings*. The labeling of the product contains the following warnings under the heading ''Warnings'':

(1) ''Abdominal cramps, nausea, vomiting, diarrhea, headache, or dizziness sometimes occur after taking this drug. If any of these conditions persist consult a doctor.''

(2) ''If you are pregnant or have liver disease, do not take this product unless directed by a doctor.''

(d) *Directions*. The labeling of the product contains the following information under the heading ''Directions'':

(1) Adults, children 12 years of age and over, and children 2 years to under 12 years of age: Oral dosage is a single dose of 5 milligrams of pyrantel base per pound, or 11 milligrams per kilogram, of body weight not to exceed 1 gram. Dosing information should be converted to easily understood directions for the consumer using the following dosage schedule:

Weight	Dosage (taken as a single dose) [1]
Less than 25 pounds or under 2 years old.	Do not use unless directed by a doctor.
25 to 37 pounds	125 milligrams.
38 to 62 pounds	250 milligrams.
63 to 87 pounds	375 milligrams.
88 to 112 pounds	500 milligrams.
113 to 137 pounds	625 milligrams.
138 to 162 pounds	750 milligrams.
163 to 187 pounds	875 milligrams.
188 pounds and over	1,000 milligrams.

[1] Depending on the product, the label should state the quantity of drug as a liquid measurement (e.g., teaspoonsful) or as the number of dosage units (e.g., tablets) to be taken for the varying body weights. (If appropriate, it is recommended that a measuring cup graduated by body weight and/or liquid measurement be provided with the product.) Manufacturers should present this information as appropriate for their product and may vary the format of this chart as necessary.

(2) ''Read package insert carefully before taking this medication. Take only according to directions and do not exceed the recommended dosage unless directed by a doctor. Medication should only be taken on time as a single dose; do not repeat treatment unless directed by a doctor. When one individual in a household has pinworms, the entire household should be treated unless otherwise advised. See Warnings. If any worms other than pinworms are present before or after treatment, consult a doctor. If any symptoms or pinworms are still present after treatment, consult a doctor.

(3) ''This product can be taken any time of day, with or without meals. It may be taken alone or with milk or fruit juice. Use of a laxative is not necessary prior to, during, or after medication.''

(e) *Optional wording*. The word ''physician'' may be substituted for the word ''doctor'' in any of the labeling statements in this section.

[51 FR 27759, Aug. 1, 1986; 52 FR 7831, Mar. 13, 1987, as amended at 53 FR 35810, Sept. 15, 1988]

§ 357.152 Package inserts for anthelmintic drug products.

The labeling of the product contains a consumer package insert which includes the following information:

(a) A discussion of the symptoms suggestive of pinworm infestation, including a statement that pinworms must be visually identified before taking this medication.

(b) A detailed description of how to find and identify the pinworm.

(c) A commentary on the life cycle of the pinworm.

(d) A commentary on the ways in which pinworms may be spread from person to person and hygienic procedures to follow to avoid such spreading.

(e) The appropriate labeling information contained in § 357.150

(Collection of information requirement approved by the Office of Management and Budget under control number 0910–0232)

[51 FR 27759, Aug. 1, 1986, as amended at 52 FR 2515, Jan 23, 1987]

§ 357.180 Professional labeling.

The labeling provided to health professionals (but not to the general public) may contain an additional indication: ''For the treatment of common roundworm infestation.''