

The amount of the \$485 fee attributable to line item 1 is \$71.295 ($.1470 \times \$485 = \71.295). The amount of the fee attributable to line item 2 is \$128.3795 ($.2647 \times \$485 = \128.3795). The amount of the fee attributable to line item 3 is \$285.277 ($.5882 \times \$485 = \285.277).

Amount of merchandise processing fee eligible for drawback per line item.

The amount of merchandise processing fee eligible for drawback for line item 1 is \$70.5821 ($.99 \times \71.295). The amount of fee eligible for drawback for line item 2 is \$127.0957 ($.99 \times \128.3795). The amount of fee eligible for drawback for line item 3 is \$282.4242 ($.99 \times \285.277).

Amount of merchandise processing fee eligible for drawback per unit of merchandise. The amount of merchandise processing fee eligible for drawback per unit of merchandise is calculated by dividing the amount of fee eligible for drawback for the line item by the number of units in the line item. For line item 1, the amount of merchandise processing fee eligible for drawback per unit is \$.0141 ($\$70.5821 \div 5,000 = \$.0141$). If 1,000 widgets form the basis of a claim for drawback under 19 U.S.C. 1313(j), the total amount of drawback attributable to the merchandise processing fee is \$14.10 ($1,000 \times .0141 = \14.10). For line item 2, the amount of fee eligible for drawback per unit is \$.0212 ($\$127.0957 \div 6,000 = \$.0212$). For line item 3, the amount of fee eligible for drawback per unit is \$.0282 ($\$282.4242 \div 10,000 = \$.0282$).

Example 2

This example illustrates the treatment of dutiable merchandise that is exempt from the merchandise processing fee and duty-free merchandise that is subject to the merchandise processing fee.

Line item 1—700 meters of printed cloth valued at \$10 per meter (total value \$70,000) that is exempt from the merchandise processing fee under 19 U.S.C. 58c(b)(8)(ii)(B)(iii)

Line item 2—15,000 articles valued at \$100 each (total value \$1,500,000)

Line item 3—10,000 duty-free articles valued at \$50 each (total value \$500,000)

The relative value ratios are calculated using line items 2 and 3 only, as there is no merchandise processing fee imposed by reason of importation on line item 1.

Line item 2— $1,500,000 \div 2,000,000 = .75$ (line items 2 and 3 form the total value of the merchandise subject to the merchandise processing fee).

Line item 3— $500,000 \div 2,000,000 = .25$

If the total merchandise processing fee paid was \$485, the amount of the fee attributable to line item 2 is \$363.75 ($.75 \times \$485 = \363.75). The amount of the fee attributable to line item 3 is \$121.25 ($.25 \times \$485 = \121.25).

The amount of drawback on the merchandise processing fee attributable to each unit of line item 2 is \$.0243 ($\$363.75 \div 15,000 = \$.0243$). The amount of drawback on the merchandise processing fee attributable to each unit of line item 3 is \$.0121 ($\$121.25 \div 10,000 = \$.0121$).

If 1,000 units of line item 2 were exported, the drawback attributable to the merchandise processing fee is \$24.23 ($\$.02423 \times 1,000 = \24.23).

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Raymond W. Kelly,
Commissioner of Customs.

Approved: November 9, 2000.

John P. Simpson,
Deputy Assistant Secretary of the Treasury.
[FR Doc. 01-3358 Filed 2-8-01; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Pyrantel Pamoate Chewable Tablets

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Blue Ridge Pharmaceuticals, Inc. The ANADA provides for use of pyrantel pamoate chewable tablets for the removal of certain gastrointestinal parasites and prevention of reinfection in puppies and dogs.

DATES: This rule is effective February 9, 2001.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0209.

SUPPLEMENTARY INFORMATION: Blue Ridge Pharmaceuticals, Inc., 4249-105 Piedmont Pkwy., Greensboro, NC 27410, filed ANADA 200-281 that provides for use of WORMEXX® (pyrantel pamoate) Chewable Tablets for the removal of certain gastrointestinal parasites and

prevention of reinfection in puppies and dogs. Blue Ridge's WORMEXX® Chewable Tablets is approved as a generic copy of Farnam Co.'s D-WORM® (pyrantel pamoate) Dog Wormer Chewable Tablets, approved under NADA 139-191. ANADA 200-281 is approved as of January 3, 2001, and 21 CFR 520.2041 is amended to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(d)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.2041 [Amended]

2. Section 520.2041 *Pyrantel pamoate chewable tablets* is amended in paragraph (b) by removing "No. 017135" and adding in its place "Nos. 017135 and 065274".

Dated: January 31, 2001.

Stephen F. Sundlof,
Director, Center for Veterinary Medicine.
[FR Doc. 01-3415 Filed 2-8-01; 8:45 am]

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