

a percentage, that is attributable to the qualifying rum.

(g) *Importer system for review of necessary recordkeeping.* The importer will establish and implement a system of internal controls which demonstrate that reasonable care was exercised in its claim for duty-free treatment under the CBI. These controls should include tests to assure the accuracy and availability of records that establish:

- (1) The origin of the rum;
- (2) The direct shipment of the rum from a beneficiary country or from the U.S. Virgin Islands to Canada;
- (3) The alcohol content of the finished liqueur/beverage imported from Canada; and
- (4) The direct shipment of the finished liqueur/beverage from Canada to the United States.

(h) *Submission of documents to Customs.* The importer must be prepared to submit directly to the port director, if requested, those documents and/or supporting records as described in paragraphs (d), (e) and (f) of this

section, for a period of 5 years from the date of entry of the related liqueurs and spirituous beverages under section 213(a)(6) of the Caribbean Basin Economic Recovery Act (19 U.S.C. 2703(a)(6)), as provided in § 163.4(a) of this chapter. If requested, the importer must submit such documents and/or supporting records to the port director within 60 calendar days of the date of the request or such additional period as the port director may allow for good cause shown.

#### PART 163—RECORDKEEPING

1. The authority citation for part 163 continues to read as follows:

**Authority:** 5 U.S.C. 301; 19 U.S.C. 66, 1484, 1508, 1509, 1510, 1624.

2. The Appendix to part 163 is amended by adding the following new listing under section IV in appropriate numerical order to read as follows:

#### Appendix to Part 163—Interim (a)(1)(A) List

\* \* \* \* \*

#### IV. \* \* \*

§ 10.199 Documents, etc. required for duty-free entry of liqueurs and/or spirituous beverages produced in Canada from CBI rum, declaration of Canadian processor (plus supporting information).

\* \* \* \* \*

#### PART 178—APPROVAL OF INFORMATION COLLECTION REQUIREMENTS

1. The authority citation for part 178 continues to read as follows:

**Authority:** 5 U.S.C. 301; 19 U.S.C. 1624; 44 U.S.C. 3501 *et seq.*

2. Section 178.2 is amended by adding the following in appropriate numerical sequence according to the section number under the columns indicated:

#### § 178.2 Listing of OMB control numbers.

19 CFR Section	Description	OMB control No.
* * * * *		
§ 10.199 .....	Claim for duty-free entry of rum beverages from Canada under the Caribbean Basin Initiative.	1515-0194
* * * * *		

Raymond W. Kelly,  
Commissioner of Customs.

Approved: February 5, 2001.

Timothy E. Skud,  
Acting Deputy Assistant Secretary of the Treasury.  
[FR Doc. 01-3360 Filed 2-8-01; 8:45 am]  
BILLING CODE 4820-02-U

#### DEPARTMENT OF THE TREASURY

##### Customs Service

##### 19 CFR Part 191

[T.D. 01-18]

RIN 1515-AC67

##### Merchandise Processing Fee Eligible To Be Claimed as Unused Merchandise Drawback

**AGENCY:** Customs Service, Department of the Treasury.

**ACTION:** Interim rule; solicitation of comments.

**SUMMARY:** This document amends the Customs Regulations on an interim basis to indicate that merchandise processing

fees are eligible to be claimed as unused merchandise drawback. The change is made to reflect a recent court decision in which merchandise processing fees were found to be assessed under Federal law and imposed by reason of importation and therefore eligible to be claimed as unused merchandise drawback pursuant to 19 U.S.C. 1313(j). The amendment will require a drawback claimant to apportion the merchandise processing fee to that merchandise that provides the basis for drawback.

**DATES:** This interim rule is effective February 9, 2001. Comments must be received on or before April 10, 2001.

**ADDRESSES:** Written comments (preferably in triplicate) may be submitted to and inspected at the Regulations Branch, Office of Regulations and Rulings, U.S. Customs Service, 1300 Pennsylvania Avenue, NW., 3rd Floor, Washington, DC 20229.

**FOR FURTHER INFORMATION CONTACT:** William G. Rosoff, Chief, Duty and Refund Determinations Branch, Office of Regulations and Rulings, U.S. Customs Service, 1300 Pennsylvania Avenue, NW., Washington, DC 20029, Tel. (202) 927-2265.

#### SUPPLEMENTARY INFORMATION:

##### Background

*Merchandise Processing Fees—19 U.S.C. 58c(a)(9)(A)*

Merchandise processing fees are fees the Secretary of the Treasury charges and collects for the processing of merchandise that is formally entered or released into the United States. See 19 U.S.C. 58c(a)(9)(A). A merchandise processing fee is assessed in an amount equal to 0.21 percent of the value of the imported merchandise, as determined under 19 U.S.C. 1401a. Merchandise processing fees are subject to two monetary limits:

(1) A cap of \$485 is imposed by 19 U.S.C. 58c(a)(9)(B)(i) for any release or entry, including weekly Free Trade Zone entries (see section 410 of the Trade and Development Act of 2000, Pub. L. 106-200, 114 Stat. 251, enacted on May 18, 2000), for which the value of merchandise subject to the fee exceeds \$230,952.38 (\$485 ÷ .0021 = \$230,952.38); and

(2) For certain monthly entries, as prescribed by Pub. L. 101-382, section 111(f), as amended, and implemented

by § 24.23(d) of the Customs Regulations (19 CFR 24.23(d)), the merchandise processing fee is limited to the lesser of the following:

(i) A cap of \$400 where the value of the merchandise subject to the fee exceeds \$190,476.19 ( $\$400 \div .0021 = \$190,476.19$ ); or

(ii) The amount determined by applying the *ad valorem* rate under paragraph (b)(1)(i)(A) of § 24.23 to the total value of such daily importations.

#### *Drawback—19 U.S.C. 1313*

Section 313 of the Tariff Act of 1930, as amended (19 U.S.C. 1313), concerns drawback and refunds. Drawback is a refund of certain duties, taxes and fees paid by the importer of record and granted to a drawback claimant under specific conditions. There are several types of drawback. Section 1313(j) concerns drawback for “unused merchandise,” and provides, pursuant to specific conditions set forth therein, that a refund of 99 percent of each duty, tax, or fee “imposed under Federal law because of [an article’s] importation” will be refunded as drawback.

#### *Merchandise Processing Fees Eligible To Be Claimed as Unused Merchandise Drawback*

The issue of whether a merchandise processing fee is “imposed under Federal law because of [an article’s] importation,” and therefore eligible to be claimed as unused merchandise drawback pursuant to the terms of section 1313(j), was recently examined by the Court of Appeals for the Federal Circuit in *Texport Oil v. United States*, 185 Fd. 3d 1291 (Fed. Cir. 1999). In that case, the court held that as merchandise processing fees are “assessed under Federal law” (pursuant to 19 U.S.C. 58c(a)(9)) and “explicitly linked to import activities,” they are imposed by reason of importation and therefore subject to unused merchandise drawback by application of the statute.

#### *Amendment to the Customs Regulations*

To implement the court’s interpretation of 19 U.S.C. 1313(j), it is necessary to amend the Customs Regulations to provide that merchandise processing fees are now subject to unused merchandise drawback, and to add apportionment language. Apportionment language is necessary because in order for a drawback claimant to correctly calculate the amount of drawback due, the claimant must apportion the merchandise processing fee to that merchandise that provides the basis for unused merchandise drawback.

In this document, Customs is amending the regulations to reflect the holding in *Texport* and to provide examples of apportionment calculations. Amendments are made to §§ 191.2(u), 191.3, and 191.51 of the Customs Regulations. Section 191.3 is amended to reflect that a merchandise processing fee is now subject to unused merchandise drawback. Section 191.51 is amended to reflect how a claimant is to calculate the portion of a merchandise processing fee that is eligible to be claimed as unused merchandise drawback. A conforming change is made to § 191.2(u). A more detailed explanation of the amendments is set forth below.

#### *19 CFR 191.3*

Section 191.3 of the Customs Regulations (19 CFR 191.3) identifies those duties and fees that are subject to, or ineligible for, drawback. Paragraph (a) of this section enumerates those duties that are subject to drawback. Paragraph (b) sets forth those duties and fees that are deemed ineligible for drawback. In paragraph (b)(2), merchandise processing fees are specifically identified as ineligible for drawback.

In view of the recent judicial interpretation of section 1313(j)(2) in which merchandise processing fees were deemed subject to unused merchandise drawback, §§ 191.3(a) and (b)(2) of the Customs Regulations are amended to reflect that determination. A new paragraph (a)(4) is added to provide that merchandise processing fees are eligible to be claimed as unused merchandise drawback. Paragraph (b)(2) is amended so as to provide that merchandise processing fees are ineligible for drawback except when unused merchandise drawback is claimed.

#### *19 CFR 191.51*

Section 191.51(b) of the Customs Regulations requires a drawback claimant to correctly calculate the amount of drawback due when completing a drawback entry.

As stated above, the court’s interpretation of 19 U.S.C. 1313(j) requires that a drawback claimant apportion a merchandise processing fee to that merchandise that provides the basis for unused merchandise drawback in order to correctly calculate the amount of drawback due.

In order for a drawback claimant to be able to ascertain what portion of a merchandise processing fee is eligible to be claimed as unused merchandise drawback, a four-step apportionment calculation is necessary. First, as with

any drawback claim where not all of the merchandise in a particular entry provides a basis for drawback, it is necessary for a claimant to calculate the value of each line item of entered merchandise subject to the fee, relative to the value of the entire entry subject to the fee. The resulting figure constitutes the “relative value ratio”. Second, the relative value ratio for each line item is multiplied by the amount of merchandise processing fee paid in connection with the entry. The resulting figures represent the amount of merchandise processing fee attributable to each line item. Third, the amount of merchandise processing fee attributable to each line item that provides the basis for unused merchandise drawback is multiplied by 99 percent. The resulting figure represents that portion of the merchandise processing fee attributable to each line item that is eligible to be claimed as unused merchandise drawback, as per section 1313(j). Lastly, in order to calculate the amount of merchandise processing fee eligible for drawback per unit of merchandise, the amount of fee that is eligible to be claimed as unused merchandise drawback per line item is divided by the number of units covered by that line item.

As § 191.51(b) requires that a drawback claimant correctly calculate the amount of drawback due, and a claim for unused merchandise drawback for a merchandise processing fee will necessarily involve an apportionment calculation, this provision is amended to reflect that fact and to provide examples of the manner by which such apportionment calculations are to be made.

#### *19 CFR 191.2(u)*

Section 191.2(u) of the Customs Regulations (19 CFR 191.2(u)) sets forth the definition of the term “relative value” for purposes of part 191.

A drawback claimant is required to calculate the “relative value ratio” when determining what portion of a merchandise processing fee is eligible for unused merchandise drawback. See the amended text of § 191.51(b) of the Customs Regulations (19 CFR 191.51(b)), discussed below. As the term “relative value ratio,” as used in § 191.51(b), as amended, does not share the same meaning as the term “relative value” as set forth in § 191.2(u), and the two terms are similar enough to potentially cause confusion, § 191.2(u) is amended so as to exclude applicability to § 191.51(b).

## Comments

Before adopting this interim regulation as a final rule, consideration will be given to any written comments timely submitted to Customs, including comments on the clarity of this interim rule and how it may be made easier to understand. Comments submitted will be available for public inspection in accordance with the Freedom of Information Act (5 U.S.C. 552), § 1.4 of the Treasury Department Regulations (31 CFR 1.4), and § 103.11(b) of the Customs Regulations (19 CFR 103.11(b)), on regular business days between the hours of 9 a.m. and 4:30 p.m. at the Regulations Branch, Office of Regulations and Rulings, U.S. Customs Service, 1300 Pennsylvania Avenue, NW., 3rd Floor, Washington, DC.

## Inapplicability of Prior Public Notice and Comment Procedures

Pursuant to the provisions of 5 U.S.C. 553(b)(B), Customs has determined that prior public notice and comment procedures on this regulation are unnecessary and contrary to public interest. The regulatory changes conform the Customs Regulations to reflect a recent decision by the Court of Appeals for the Federal Circuit. In addition, the regulatory changes benefit the public by allowing merchandise processing fees to be claimed as unused merchandise drawback, and by providing specific information as to how a drawback claimant is to correctly calculate that portion of a merchandise processing fee that is eligible to be claimed as unused merchandise drawback. For these reasons, pursuant to the provisions of 5 U.S.C. 553(d)(1) and (3), Customs finds that there is good cause for dispensing with a delayed effective date.

## Executive Order 12866

This document does not meet the criteria for a "significant regulatory action" as specified in Executive Order 12866.

## Regulatory Flexibility Act

Because no notice of proposed rulemaking is required for this rule, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply.

## Drafting Information

The principal author of this document was Suzanne Kingsbury, Regulations Branch, Office of Regulations and Rulings, U.S. Customs Service. However, personnel from other offices participated in its development.

## List of Subjects

### 19 CFR Part 191

Claims, Commerce, Customs duties and inspection, Drawback.

## Amendment to the Regulations

For the reason stated above, part 191 of the Customs Regulations (19 CFR part 191), is amended as set forth below.

## PART 191—DRAWBACK

1. The general authority citation for part 191 continues to read as follows:

**Authority:** 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 20, Harmonized Tariff Schedule of the United States), 1313, 1624.

\* \* \* \* \*

2. Section 191.2(u) is amended by adding the words “, except for purposes of § 191.51(b),” after the word “means” in the first sentence.

3. Section 191.3 is amended:

a. In paragraph (a), introductory text, by adding the words “and fees” after the word “Duties”;

b. At the end of paragraph (a)(1)(ii), by adding the word “and” after the semicolon;

c. At the end of paragraph (a)(2), by removing the word “and”;

d. At the end of paragraph (a)(3), by removing the period and adding in its place “; and”;

e. By adding a new paragraph (a)(4); and

f. By revising paragraph (b)(2).

The addition and revision read as follows:

### § 191.3 Duties and fees subject or not subject to drawback.

(a) \* \* \*

(4) Merchandise processing fees (see § 24.23 of this chapter) for unused merchandise drawback pursuant to 19 U.S.C. 1313(j).

(b) \* \* \*

(2) Merchandise processing fees (see § 24.23 of this chapter), except where unused merchandise drawback is claimed; and

\* \* \* \* \*

4. Section 191.51(b) is amended by redesignating the existing text as paragraph (b)(1), adding a heading to newly redesignated paragraph (b)(1), and adding a new paragraph (b)(2) to read as follows:

### § 191.51 Completion of drawback claims.

\* \* \* \* \*

(b) *Drawback due.*—(1) *Claimant required to calculate drawback.* \* \* \*

(2) *Merchandise processing fee apportionment calculation.* Where a drawback claimant seeks unused merchandise drawback pursuant to 19

U.S.C. 1313(j) for a merchandise processing fee paid pursuant to 19 U.S.C. 58c(a)(9)(A), the claimant is required to correctly apportion the fee to that merchandise that provides the basis for drawback when calculating the amount of drawback requested on the drawback entry. This is determined as follows:

(i) *Relative value ratio for each line item.* The value of each line item of entered merchandise subject to a merchandise processing fee is calculated (to four decimal places) by dividing the value of the line item subject to the fee by the total value of entered merchandise subject to the fee. The resulting value forms the relative value ratio.

(ii) *Merchandise processing fee apportioned to each line item.* To apportion the merchandise processing fee to each line item, the relative value ratio for each line item is multiplied by the merchandise processing fee paid.

(iii) *Amount of merchandise processing fee eligible for drawback per line item.* The amount of merchandise processing fee apportioned to each line item is multiplied by 99 percent to calculate that portion of the fee attributable to each line item that is eligible for drawback.

(iv) *Amount of merchandise processing fee eligible for drawback per unit of merchandise.* To calculate the amount of a merchandise processing fee eligible for drawback per unit of merchandise, the line item amount that is eligible for drawback is divided by the number of units covered by that line item (to two decimal places).

### Example 1

Line item 1—5,000 articles valued at \$10 each total \$50,000  
Line item 2—6,000 articles valued at \$15 each total \$90,000  
Line item 3—10,000 articles valued at \$20 each total \$200,000  
Total units = 21,000  
Total value = \$340,000  
Merchandise processing fee = \$485 (for purposes of this example, the fee cap of \$485, as per 19 U.S.C. 58c(a)(9)(B)(i), is applicable)

*Line item relative value ratios.* The relative value ratio for line item 1 is calculated by dividing the value of that line item by the total value (\$50,000 ÷ 340,000 = .1470). The relative value ratio for line item 2 is .2647. The relative value ratio for line item 3 is .5882.

*Merchandise processing fee apportioned to each line item.* The amount of fee attributable to each line item is calculated by multiplying \$485 by the applicable relative value ratio.

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 ( $\$70.5821 \div 5,000 = \$0.0141$ ). 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 ( $\$127.0957 \div 6,000 = \$0.0212$ ). For line item 3, the amount of fee eligible for drawback per unit is \$.0282 ( $\$282.4242 \div 10,000 = \$0.0282$ ).

*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 ( $\$363.75 \div 15,000 = \$0.0243$ ). The amount of drawback on the merchandise processing fee attributable to each unit of line item 3 is \$.0121 ( $\$121.25 \div 10,000 = \$0.0121$ ).

If 1,000 units of line item 2 were exported, the drawback attributable to the merchandise processing fee is \$24.23 ( $\$0.0243 \times 1,000 = \$24.23$ ).

\* \* \* \* \*

**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]

**BILLING CODE 4820-02-P**

## 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]

**BILLING CODE 4160-01-F**