SEC (x/xx) Persons who potentially are to respond to the collection of information contained in this form are not required to respond unless the form displays a currently valid OMB control number.

Form ID—General Instructions

Using and Preparing Form ID

Use Form ID to apply for or to amend the following EDGAR codes:

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CIK Confirmation Code (CCC)—You will use the CCC in the header of your filings in conjunction with your CIK to ensure that you authorized the filing

Password (PW)—The PW allows you to log onto the EDGAR system, submit filings, and change your CCC

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Please see the EDGAR Filer Manual for instructions on how to file electronically, including how to use the access codes

You must complete all items in any parts which apply to you. If any item in any part does not apply to you, please mark that part "NA." If your form is incomplete, it may take us longer to assign your access codes

Part I—Applicant Information (to be completed by all applicants)

Please check the appropriate box to indicate whether you will be sending electronic submissions as a filer, filing agent, or training agent. Mark only one of these boxes per application. A "filer" is any person or entity on whose behalf an electronic filing is made. A "filing agent" is a financial printer, law firm, or other party which will be using these access codes to send a filing or portion of a filing on behalf of a filer. A "training agent" is any person or entity which will be sending only test filings in conjunction with training other persons.

If you do not already have access codes, please mark the ''Initial application'' box, and complete all other items in Parts II through V that apply to you.

If you already have access codes, please provide your CIK in the upper left corner, and mark the boxes to indicate the reason you are filing the amendment and any access codes you want to replace. You also should complete Part V (signature) and those items in Parts II through IV which have changed from the previous application. You may change your access codes (except your PMAC) and most other information on Form ID electronically via EDGAR. See the EDGAR Filer Manual for details.

Part II—Filer Information (to be completed by filers only)

The registrant's tax or federal identification number is the number issued by the Internal Revenue Service. Foreign private issuers should include all zeroes if they do not have a tax or federal identification number. (We do not require this number for individuals.) We do not require state of incorporation/ organization or fiscal year end for individuals. We request that foreign private issuers include their country of organization.

Part III—Contact Information (to be completed by all applicants)

In this section, identify the individual who should receive the access codes and EDGAR-related information.

If you are or become an EDGAR Private Mail subscriber, you can receive acceptance and suspension messages and any requested return copies of your filings via electronic mail at your expense. If you do not subscribe to EDGAR Private Mail, you can receive your acceptance and suspension messages via Internet E-Mail if you provide an address. We will not send return copies of filings to an Internet address.

Part IV—Account Information (to be completed by filers and filing agents only) Identify in this section the individual who should receive account information and/or billing invoices from us. We will use this information to electronically process fee payments and billings.

Part V—Signature (to be completed by all applicants)

Send your manually signed and dated form to: Branch of Filer Support, U.S. Securities and Exchange Commission, Operations Center, Stop 0–7, 6432 General Green Way, Alexandria, VA 22312.

Dated: October 7, 1999. By the Commission.

# Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 99–26985 Filed 10–19–99; 8:45 am] BILLING CODE 8010–01–P

# **DEPARTMENT OF THE TREASURY**

**Customs Service** 

19 CFR Parts 24, 159 and 174

[T.D. 99-75]

RIN 1515-AB76

Interest on Underpayments and Overpayments of Customs Duties, Taxes, Fees and Interest

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

**ACTION:** Interim rule.

SUMMARY: This document conforms the Customs Regulations to existing statutory provisions and judicial precedent regarding the assessment of interest due to underpayments or overpayments to Customs of duties, taxes and fees pertaining to imported merchandise, including interest thereon. The majority of the conforming changes reflect the terms of section 505 of the Tariff Act of 1930 (19 U.S.C. 1505), as amended by section 642(a) within the

Customs Modernization provisions of the North American Free Trade Agreement Implementation Act. Under that statute, interest accrues initially from the date the duties, taxes, fees and interest are deposited with Customs in the case of overpayments, or are required to be deposited with Customs in the case of underpayments, but in either case not beyond the date of liquidation or reliquidation of the applicable entry or reconciliation. Also under the statute and applicable judicial precedent, all bills issued by Customs for underpayments of duties, taxes, fees and interest are due within 15 or 30 days of issuance. In addition, the document conforms the Customs Regulations to other changes to 19 U.S.C. 1505 and to section 321 of the Tariff Act of 1930 (19 U.S.C. 1321) regarding interest that were made by sections 2(a) and 3(a)(12) of the Miscellaneous Trade and Technical Corrections Act of 1996.

**DATES:** Interim rule effective October 20, 1999. Comments must be received on or before December 20, 1999.

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

**FOR FURTHER INFORMATION CONTACT:** Robert Reiley, Financial Management Division (202–927–1504).

SUPPLEMENTARY INFORMATION:

# **Background**

Present Regulatory Provisions

The regulatory provisions amended by this document are as follows:

Section 24.1 of the Customs Regulations (19 CFR 24.1) sets forth general procedures governing the collection of "Customs duties, taxes, and other charges," including the permissible methods of payment.

Section 24.3 of the Customs
Regulations (19 CFR 24.3) sets forth
general provisions regarding the
rendering and payment of bills or
accounts for money due the United
States and the issuance of receipts
therefor. Paragraph (e) of that section
provides that (1) a bill for increased or
additional duties determined to be due
upon a liquidation or reliquidation is
due 15 days from the date of such
liquidation or reliquidation and (2) all
other bills are due and payable upon the
bill date appearing on the bill.

Section 24.3a of the Customs Regulations (19 CFR 24.3a) contains detailed provisions regarding Customs bills for supplemental duties (increased or additional duties assessed upon liquidation or reliquidation), reimbursable services, and miscellaneous amounts (bills other than duties, taxes, reimbursable services, liquidated damages, fines, and penalties), including interest thereon.

Section 24.11 of the Customs Regulations (19 CFR 24.11) concerns the issuance of bills for "increased or additional duties or taxes found due upon liquidation" and provides for issuance of such bills to the importer of record or, in certain circumstances, to the actual owner.

Section 24.25 of the Customs Regulations (19 CFR 24.25) concerns statement processing and automated clearinghouse filing and payment procedures and, in the second sentence of paragraph (a), refers to a single payment of "duties, taxes and fees."

Section 24.36 of the Customs Regulations (19 CFR 24.36) concerns refunds of excessive duties or taxes, and paragraph (a) thereof specifically provides for preparation of a refund "[w]hen it is found on liquidation or reliquidation of an entry that a refund of excessive duties or taxes, or both, is due."

Section 159.6 of the Customs Regulations (19 CFR 159.6) concerns the treatment by Customs of differences of less than \$20 and \$20 or more, between estimated deposits and amounts assessed on liquidation. This section specifically refers in these contexts to "duties, fees, and taxes" or to "duties and fees and internal revenue taxes."

Section 174.11 of the Customs Regulations (19 CFR 174.11) sets forth the matters that may be the subject of an administrative protest. Paragraph (c) of that section specifically refers to "charges or exactions" of whatever character within the jurisdiction of the Secretary of the Treasury.

Section 174.12 of the Customs Regulations (19 CFR 174.12) sets forth the procedures for filing a protest. Paragraph (a)(2) of that section provides that a protest may be filed by any person "paying any charge or exaction."

# Customs Modernization Statutory Changes

The Customs Modernization provisions contained in Title VI of the North American Free Trade Agreement Implementation Act ("the Act"), Public Law 103–182, 107 Stat. 2057, included, in section 642(a), an extensive amendment of section 505 of the Tariff Act of 1930 (19 U.S.C. 1505). Prior to

this amendment, section 505 consisted of three subsections covering the deposit of estimated duties (subsection (a)), the collection of increased or additional duties and the refund of excess duties deposited as determined on a liquidation or reliquidation (subsection (b)), and the due date for duties determined to be due upon liquidation or reliquidation, delinquency, and interest on delinquent duty payments (subsection (c)). Section 505, as amended by section 642(a) of the Act, now contains the following provisions:

1. Subsection (a) of amended section 505 requires the importer of record to deposit with Customs, at the time of making entry or at such later time as the Secretary of the Treasury may prescribe by regulation, the amount of duties "and fees" estimated to be payable on the entry. In addition, subsection (a) now provides (1) that the regulations prescribed by the Secretary may provide that estimated duties and fees shall be deposited before or at the time an import activity summary statement is filed and (2) that if an import activity summary statement is filed, the estimated duties and fees shall be deposited together with interest, at a rate determined by the Secretary of the Treasury, accruing from the first date of the month the statement is required to be filed until the date such statement is actually filed. (An import activity summary statement is a filing procedure provided for in section 484 of the Tariff Act of 1930, as amended [19 U.S.C. 1484], and was added by section 637(a) of the Act to permit the filing of a single statement, covering entry or warehouse withdrawal transactions made during a calendar month, within such time period as prescribed by the Secretary of the Treasury by regulation but not later than the 20th day following such calendar month. Implementation of the import activity summary statement procedure will be the subject of a separate regulatory action and thus is not dealt with in this document.) Thus, in order to avoid a potential conflict with the import activity summary statement procedure, subsection (a), as amended, no longer contains a 30-day limitation on the authority of the Secretary of the Treasury to prescribe by regulation for the deposit of estimated duties after the date of entry

2. Subsection (b) of amended section 505 requires Customs to collect any increased or additional duties "and fees due, together with interest thereon," and to "refund any excess moneys deposited, together with interest thereon," as determined on a liquidation or reliquidation. In addition,

subsection (b) now provides (1) that duties, fees, and interest determined to be due upon liquidation or reliquidation are due 30 days after issuance of the bill for payment and (2) that refunds of excess moneys deposited, together with interest thereon, shall be paid within 30 days of liquidation or reliquidation. Thus, in addition to the inclusion of new references to the collection of fees and interest, to the refund of excess "moneys" (which would include fees) and interest thereon, and to a due date based on the issuance of a bill, section 505, as amended, prescribes a specific time limit for the payment of refunds and no longer provides that duties determined to be due upon liquidation or reliquidation shall be due 15 days after the date of that liquidation or reliquidation (see also the discussion of subsection (d) below).

3. Subsection (c) of amended section 505 is essentially new and provides (1) that interest assessed due to an underpayment of duties, fees, or interest shall accrue, at a rate determined by the Secretary of the Treasury, from the date the importer of record is required to deposit estimated duties, fees, and interest to the date of liquidation or reliquidation of the applicable entry or reconciliation and (2) that interest on excess moneys deposited shall accrue, at a rate determined by the Secretary of the Treasury, from the date the importer of record deposits estimated duties, fees, and interest to the date of liquidation or reliquidation of the applicable entry or reconciliation. (Reconciliation is a procedure provided for in section 484 of the Tariff Act of 1930, as amended [19 U.S.C. 1484], and was added by section 637(a) of the Act to allow elements of an electronic entry summary or electronic import activity summary statement oother than those elements related to the admissibility of the merchandise], if undetermined at the time the summary or statement is filed, to be provided to Customs at a later time. Reconciliation will be implemented by separate regulatory action and thus is not substantively addressed in this document.) Thus, the importer of record is liable for interest on underpaid amounts from the date those amounts should have been paid to Customs, and, conversely, the importer of record is entitled to interest on refunds of payments made to Customs in excess of the amount properly due.

4. Finally, subsection (d) of amended section 505 provides (1) that if duties, fees, and interest determined to be due or refunded are not paid in full within the 30-day period specified in subsection (b), any unpaid balance shall be considered delinquent and bear

interest by 30-day periods, at a rate determined by the Secretary of the Treasury, from the date of liquidation or reliquidation until the full balance is paid and (2) that no interest shall accrue during the 30-day period in which payment is actually made. In addition, subsection (d) of amended section 505 reflects the terms of present § 24.3a(c)(3) of the regulations in that it provides for a 30-day period for payment both before and once a delinquency occurs, during which period no additional interest (that is, on any outstanding principal amount, plus interest thereon) will accrue so long as full payment of the amount outstanding is made during that current 30-day period. Thus, section 505 no longer allows for delinquency and interest accrual only after 45 days following liquidation or reliquidation. This is because the statutory delinquency period is now 30 days and because under the statute initial interest accrual on underpayments runs from the date of required deposit of moneys rather than only when a delinquency has occurred.

Customs has determined that the changes to section 505 effected by section 642(a) of the Act as described above require a number of conforming changes to the provisions of §§ 24.1, 24.3, 24.3a, 24.11, 24.25 and 24.36 of the regulations. These changes, which are explained in more detail below. concern principally the inclusion of references to the following: the collection or deposit of (estimated) fees and interest; the collection of increased or additional fees; the refund of excess fees deposited; the accrual of interest on underpaid and overpaid duties, fees and interest from the date of required (including actual) deposit to the date of liquidation or reliquidation and the collection or refund of such accrued interest; and the 30-day due date periods for payments or refunds of underpaid or overpaid duties, fees and interest as determined on liquidation or reliquidation. In addition, some of these regulatory provisions, as well as §§ 174.11 and 174.12 of the regulations, are in need of additional wording changes, involving principally the addition of references to "interest" or "taxes" or "refunds," in order to conform the regulatory texts to the principles reflected in applicable judicial decisions; these changes are also explained in more detail below.

Additional Statutory Changes Regarding Interest

Subsequent to the changes to section 505 effected by section 642(a) of the Act as discussed above, additional statutory changes regarding interest were enacted

as part of the Miscellaneous Trade and Technical Corrections Act of 1996 ("the Miscellaneous Act"), Public Law 104– 295, 110 Stat. 3514. These statutory changes, which require conforming regulatory changes, were as follows:

1. Section 2(a) of the Miscellaneous Act amended section 505(c) to provide that, in the case of a claim under 19 U.S.C. 1520(d) (that is, a NAFTA postimportation claim for a refund of duty), interest on the excess money deposited shall accrue from the date on which the claim is made; under section 2(b) of the Miscellaneous Act, the section 2(a) amendment applies to claims made on or after June 7, 1996. Since this statutory amendment relates only to interest on excess deposits, Customs believes that it should be reflected in the § 24.36 refund provisions.

2. Section 3(a)(12) of the Miscellaneous Act amended section 321(a) of the Tariff Act of 1930 (19 U.S.C. 1321(a)) by the addition of several references to "interest." The addition of these references extends the authority of the Secretary of the Treasury to include interest in determining what is a de minimis amount when providing by regulation for waiving the collection of *de minimis* amounts on entered merchandise and for disregarding *de minimis* differences between the total estimated deposit or tentatively assessed amount and the total amount actually accruing on an entry of merchandise; under section 3(b) of the Miscellaneous Act, the section 3(a)(12) amendments apply as of December 8, 1993. Customs believes that the statutory amendment pertaining to the disregarding of differences between the total estimated deposit or tentatively assessed amount (that is, of duties, fees, and taxes) and the total amount (of duties, fees, taxes, and interest) actually accruing (which is normally determined upon liquidation of the entry) should be reflected in § 159.6 of the regulations which implements this aspect of the section 321(a) provisions.

# **Explanation of Amendments**

The specific regulatory amendments set forth in this document are explained in more detail below.

# Section 24.1

The amendments to § 24.1 involve the addition of references to "fees" and "interest" in various paragraphs under the section. This is simply intended to reflect the inclusion of these terms in the text of section 505 as amended by section 642(a) of the Act. Since § 24.1 sets forth general rules for collection (including payment method) of funds

due Customs and thus covers both initial payments and supplemental payments pursuant to a bill issued by Customs, the added "interest" references are intended to cover (1) any interest that may be initially due on estimated duties and fees under the import activity summary statement procedure mentioned above to be implemented later and (2) any interest assessed on underpayments and delinquent payments of principal amounts and interest thereon under § 24.3a. However, no reference to "interest" has been added in paragraph (a)(7) of § 24.1 because this paragraph concerns initial credit or charge card payments on non-commercial transactions, which would never involve an interest payment.

#### Section 24.3

The first sentence of  $\S 24.3(b)$  is amended by adding references to the payment of estimated "fees" and "interest" in order to align the text on the terminology used in amended section 505. The words "if applicable" have been included after the added "interest" reference in recognition of the fact that interest would be required in an estimated payment circumstance only in some cases. A reference to the payment of estimated "taxes" has also been added to this regulatory text in order to reflect the fact that Customs collects taxes (e.g. harbor maintenance taxes) at the time of entry as part of the entry/liquidation process. Prior to the United States Supreme Court decision in United States Shoe Corp. v. United States, 118 S. Ct. 1290 (1998), Customs considered such harbor maintenance assessments to be "fees." However, the Supreme Court held that such assessments are "taxes." Since Customs continues to be required by law to collect such assessments and other taxes, the regulations are being amended to reflect accurately the fact that Customs collects taxes at entry.

In addition, the text of § 24.3(e) has been revised. The text revision involves the following changes: (1) in the first sentence, the addition of references to bills for "fees" and "interest" and the inclusion of a statement that bills are due and payable "within 30 days of the date of issuance of the bill"; (2) the elimination of the outdated second sentence (which provided that a bill for increased or additional duties is due 15 days from the date of liquidation or reliquidation); and (3) the inclusion of an exception for bills resulting from dishonored checks or from dishonored Automated Clearinghouse (ACH) transactions, for which the revised text prescribes a 15-day bill payment period

(see also the changes to § 24.3a regarding debit vouchers as discussed and set forth below). The last change reflects Customs' practice of requiring that bills for dishonored checks or dishonored ACH transactions be paid within 15 days of issuance of the bill. Interest assessments on such dishonored payments are provided for in the amendments to § 24.3a and are authorized because there is no statutory provision to the contrary. See *Billings* v. *United States*, 232 U.S. 261 (1914) and *United States* v. *Goodman*, 572 F. Supp. 1284 (CIT 1983).

#### Section 24.3a

In § 24.3a, the paragraph (a) discussion of supplemental duties has been modified to align on the terminology used in subsection (b) of amended section 505 and to reflect the considerations regarding taxes set forth above. Specifically, the words "taxes and fees" have been included after "duties" in two places, the words "increased or" have been included before "additional duties" within the parentheses, and the words "together with interest thereon," have been included after the parenthetical reference.

In addition, paragraph (b)(2) of § 24.3a has been revised to conform to the terms of amended section 505 regarding the accrual of interest on underpayments of duties, fees, and interest. In the revised text, paragraph (b)(2)(i), which concerns interest on initial underpayments and relates to subsection (c) of section 505, incorporates a number of illustrative examples and is further subdivided into subparagraphs (A), (B) and (C) in order to cover factual situations that arise under current Customs transaction practices and that of necessity will result in variations in the interest computation period under the basic statutory rule: subparagraph (A) concerns pre-liquidation excessive refunds; subparagraph (B) describes three scenarios involving preliquidation additional deposits; and subparagraph (C) concerns cases in which Customs receives a debit voucher indicating that a payment to Customs was not made because of a dishonored check or ACH transaction. Paragraph (b)(2)(ii) concerns interest on overdue bills and is based on subsection (d) of section 505.

# Section 24.11

Section 24.11 has been modified by removing former paragraph (b) which affected only internal Customs procedures that are not appropriate for regulatory treatment. In addition, the remaining text (former paragraph (a)) has been simplified and references to increased or additional "fees" and "interest" have been inserted in the text and in the section heading.

#### Section 24.25

In § 24.25, the second sentence of paragraph (a) has been amended to reflect that interest may be due on a statement processing transaction.

#### Section 24.36

Section 24.36 is amended by revising the first sentence of paragraph (a), by adding a new sentence at the end of paragraph (a) followed by new paragraphs (a)(1)-(a)(3), by making wording changes in the first sentence of paragraph (b), and by making similar wording changes in paragraph (c). These changes reflect the amended section 505 provisions regarding the refund of excess moneys deposited and thus include the addition of references to the refund of excessive "fees" and "interest" and to the 30-day deadline for timely refunds, as provided for in section 505(b). Similar to the approach taken in § 24.3a(b)(2)(i) as discussed above, the modified § 24.36 text incorporates a number of illustrative examples and sets forth several scenarios, involving pre-liquidation additional excess deposits and preliquidation refunds, that arise in practice and require variations to the interest computation period under the basic statutory rule. The modified § 24.36 text also includes a specific reference to interest accrual in the case of a claim for a refund filed under 19 U.S.C. 1520(d) and Subpart D of Part 181 of the Customs Regulations; this change reflects the amendment to section 505(c) effected by section 2(a) of the Miscellaneous Act as discussed above. Finally, the changes incorporate the 30-day interest period provisions for delinquent refunds as provided for in section 505(d).

# Section 159.6

A reference to "interest" has been added in each place where reference is made to duties, fees, and taxes assessed or found due in a liquidation or reliquidation context, to reflect the change to section 321(a) effected by section 3(a)(12) of the Miscellaneous Act as discussed above.

#### Sections 174.11 and 174.12

In § 174.11, a specific reference to the accrual of interest has been added in paragraph (c) to reflect that interest is a charge or exaction subject to protest within 90 days of the decision concerning such accrual. See *New Zealand Lamb Co. Inc.* v. *United States*,

40 F.3d 377 (Fed. Cir. 1994); *Syva Co.* v. *United States*, 681 F. Supp. 885 (CIT 1988); and *Travenol Laboratories Inc.* v. *United States*, 118 F.3d 749 (Fed. Cir. 1997). In addition, a reference to receiving a refund has been added in paragraph (a)(2) of § 174.12. These two changes clarify that both the assessment and the refund (or non-refund) of interest are protestable decisions.

#### **Comments**

Before adopting these interim regulations 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, Treasury Department Regulations (31 CFR 1.4), and § 103.11(b), Customs Regulations (19 CFR 103.11(b)), on normal 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, N.W., 3rd Floor, Washington, D.C.

# Inapplicability of Prior Public Notice and Comment Procedures and Delayed Effective Date Requirements

Pursuant to the provisions of 5 U.S.C. 553(b)(B), Customs has determined that prior public notice and comment procedures on these regulations are unnecessary and contrary to the public interest. The regulatory changes correct the Customs Regulations by conforming them to the terms of statutory provisions, and to the principles reflected in judicial decisions, that are currently in effect. In addition, in some cases, the changes conform the regulatory provisions to longstanding Customs administrative procedures and practices that confer benefits on, or otherwise militate in favor of, the general public. For the same 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 E.O. 12866.

# **Regulatory Flexibility Act**

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

# List of Subjects

19 CFR Part 24

Accounting, Claims, Customs duties and inspection, Interest, Taxes, User fees, Wages.

## 19 CFR Part 159

Computer technology, Customs duties and inspection, Entry, Imports, Liquidation.

#### 19 CFR Part 174

Administrative practice and procedure, Customs duties and inspection, Protests.

# Amendments to the Regulations

For the reasons stated in the preamble, Parts 24, 159 and 174 of the Customs Regulations (19 CFR Parts 24, 159 and 174) are amended as set forth below.

# PART 24—CUSTOMS FINANCIAL AND **ACCOUNTING PROCEDURE**

1-2. The general authority citation for Part 24 is revised, and the specific authority citation for § 24.24 is removed. and the specific authority citations for §§ 24.1, 24.11 and 24.36 continue to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 58a-58c, 66, 1202 (General Note 20, Harmonized Tariff Schedule of the United States), 1505, 1624; 26 U.S.C. 4461, 4462; 31 U.S.C. 9701.

Section 24.1 also issued under 19 U.S.C. 197, 198, 1648;

Section 24.11 also issued under 19 U.S.C. 1485(d);

Section 24.36 also issued under 26 U.S.C. 6423.

# § 24.1 [Amended]

- 3. In § 24.1:
- a. The section heading is amended by adding "fees, interest," after "taxes,"; b. The introductory text of paragraph
- (a) is amended by adding "fees, interest," after "taxes,";
- c. The first sentence of paragraph (a)(3)(i) is amended by adding "fees,
- interest," after "taxes,";
  d. The first sentence of paragraph (a)(7) is amended by adding ", fees," after "taxes";
- e. The first sentence of the introductory text of paragraph (b) is amended by adding "fees, interest," after "taxes,";
  f. Paragraph (b)(3) is amended by
- adding "fees," after "taxes,";
- g. Paragraph (d) is amended by adding "fees, interest," after "taxes,"; and
- h. In paragraph (e), the first sentence is amended by adding ", interest," after "fees" and the second sentence is amended by adding ", fees, interest," after "taxes"
- 4. In § 24.3, the first sentence of paragraph (b) is amended by adding ' taxes, fees, and interest, if applicable,' after "duties" and paragraph (e) is revised to read as follows:

# § 24.3 Bills and accounts; receipts.

(e) Except for bills resulting from dishonored checks or dishonored Automated Clearinghouse (ACH) transactions, all other bills for duties, taxes, fees, interest, or other charges are due and payable within 30 days of the

date of issuance of the bill. Bills resulting from dishonored checks or dishonored ACH transactions are due within 15 days of the date of issuance of the bill.

- 5. In § 24.3a:
- a. The section heading is revised;
- b. Paragraph (a) is amended by removing the words "Supplemental duties (additional duties assessed upon liquidation or reliquidation)," and adding, in their place, the words "supplemental duties, taxes and fees (increased or additional duties, taxes and fees assessed upon liquidation or reliquidation) together with interest thereon,"; and
  - c. Paragraph (b)(2) is revised. The revisions read as follows:

## § 24.3a Customs bills; interest assessment; delinquency; notice to principal and surety.

(b) \* \* \*

(2) Interest on supplemental duties, taxes, fees, and interest—(i) Initial interest accrual. Except as otherwise provided in paragraphs (b)(2)(i)(A) through (b)(2)(i)(C) of this section, interest assessed due to an underpayment of duties, taxes, fees, or interest shall accrue from the date the importer of record is required to deposit estimated duties, taxes, fees, and interest to the date of liquidation or reliquidation of the applicable entry or reconciliation. An example follows:

Example: Entry underpaid as determined upon liquidation

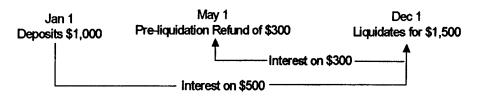


Importer owes \$500 plus interest as follows: The importer makes a \$1,000 initial deposit on the required date (January 1) and the entry liquidates for \$1,500 (December 1). Upon liquidation, the importer will be billed for \$500 plus interest. The interest will accrue from the date payment was due (January 1) to date of liquidation (December 1).

(A) If a refund of duties, taxes, fees, or interest was made prior to liquidation or reliquidation and is determined upon liquidation or reliquidation to be excessive, in addition to any other interest accrued under this paragraph (b)(2)(i), interest also shall accrue on the

excess amount refunded from the date of the refund to the date of liquidation or reliquidation of the applicable entry or reconciliation. An example follows:

Example: Pre-liquidation refund but entry liquidates for an increase



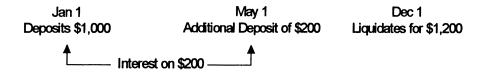
Importer owes \$800 plus interest as follows: The importer makes a \$1,000 initial deposit on the required date (January 1) and receives a pre-liquidation refund of \$300 (May 1) and the entry liquidates for \$1,500 (December 1). Upon liquidation, the importer will be billed for \$800 plus interest. The interest accrues in two segments: (1) On the original underpayment (\$500) from the date of deposit (January 1) to the date of liquidation (December 1); and (2) on the pre-liquidation

refund (\$300) from the date of the refund (May 1) to the date of liquidation (December

- (B) The following rules shall apply in the case of an additional deposit of duties, taxes, fees, or interest made prior to liquidation or reliquidation:
- (1) If the additional deposit is determined upon liquidation or reliquidation of the applicable entry or

reconciliation to constitute the correct remaining balance that was required to be deposited on the date the deposit was due, interest shall accrue on the amount of the additional deposit only from the date of the initial deposit until the date the additional deposit was made. An example follows:

Example: Additional deposit made and entry liquidates for total amount deposited

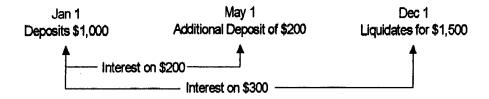


Importer owes interest on \$200 as follows: The importer makes a \$1,000 initial deposit on the required date (January 1) and an additional pre-liquidation deposit of \$200 (May 1) and the entry liquidates for \$1,200 (December 1). Upon liquidation, the importer will be billed for interest on the original \$200 underpayment from the date of the initial deposit (January 1) to the date of the additional deposit (May 1).

(2) If the additional deposit is determined upon liquidation or reliquidation of the applicable entry or reconciliation to be less than the full balance owed on the amount initially required to be deposited, in addition to any other interest accrued under this paragraph (b)(2)(i), interest also shall

accrue on the remaining unpaid balance from the date deposit was initially required to the date of liquidation or reliquidation. An example follows:

Example: Additional deposit made and entry underpaid as determined upon liquidation



Importer owes \$300 plus interest as follows:

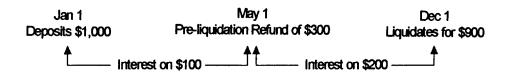
The importer makes a \$1,000 initial deposit on the required date (January 1) and an additional pre-liquidation deposit of \$200 (May 1) and the entry liquidates for \$1,500 (December 1). Upon liquidation, the importer will be billed for \$300 plus interest. The interest accrues in two segments: (1) on the additional deposit (\$200), from the date deposit was required (January 1) to the date

of the additional deposit (May 1); and (2) on the remaining underpayment (\$300), from the date deposit was required (January 1), to the date of liquidation (December 1).

(3) If an entry or reconciliation is determined upon liquidation or reliquidation to involve both an excess deposit and an excess refund made prior to liquidation or reliquidation, interest

in each case shall be computed separately and the resulting amounts shall be netted for purposes of determining the final amount of interest to be reflected in the underpaid amount. An example follows:

Example: Excess pre-liquidation deposit and excess pre-liquidation refund



Importer owes \$200 plus or minus net interest as follows:

The importer makes a \$1,000 initial deposit on the required date (January 1) and receives a pre-liquidation refund of \$300 (May 1) and the entry liquidates for \$900 (December 1). Upon liquidation, the importer will be billed for \$200 plus or minus net interest. The interest accrues in two segments: (1) Interest accrues in favor of the importer on the initial overpayment (\$100) from the date of deposit (January 1) to the date of the refund (May 1); and (2) interest accrues in favor of the Government on the refund overpayment (\$200) from the date of

the refund (May 1) to the date of liquidation (December 1).

(4) If the additional deposit or any portion thereof is determined upon liquidation or reliquidation of the applicable entry or reconciliation to constitute a payment in excess of the amount initially required to be deposited, the excess deposit shall be treated as a refundable amount on which interest also may be payable (see § 24.36).

(C) If a depository bank notifies Customs by a debit voucher that a Customs account is being debited due to a dishonored check or dishonored Automated Clearinghouse (ACH) transaction, interest shall accrue on the debited amount from the date of the debit voucher to either the date of payment of the debt represented by the debit voucher or the date of issuance of a bill for payment, whichever date is earlier

- (ii) Interest on overdue bills. If duties, taxes, fees, and interest are not paid in full within the applicable period specified in § 24.3(e), any unpaid balance shall be considered delinquent and shall bear interest until the full balance is paid.
- Section 24.11 is revised to read as follows:

# § 24.11 Notice to importer or owner of increased or additional duties, taxes, fees and interest

Any increased or additional duties, taxes, fees or interest found due upon liquidation or reliquidation shall be billed to the importer of record, or to the actual owner if the following have been filed with Customs:

- (a) A declaration of the actual owner in accordance with section 485(d), Tariff Act of 1930, as amended (19 U.S.C. 1485(d)), and § 141.20 of this chapter; and
- (b) A bond on Customs Form 301 in accordance with § 141.20 of this chapter.

#### § 24.25 [Amended]

- 7. In § 24.25, the second sentence of paragraph (a) is amended by removing the words "and fees" and adding, in their place, the words ", fees, and interest".
  - 8. In § 24.36:
- a. Paragraph (a) is amended by revising the first sentence, adding a new sentence at the end and adding new paragraphs (a)(1) through (a)(3);
- b. The first sentence of paragraph (b) is amended by removing the words "duties or taxes" and adding, in their place, the words "duties, taxes, fees or interest"; and
- c. Paragraph (c) is amended by removing the words "duties or internal revenue taxes" and adding, in their place, the words "duties, taxes, fees or interest".

The revisions and additions read as follows:

# § 24.36 Refunds of excessive duties, taxes, etc.

(a) When it is found upon, or prior to, liquidation or reliquidation of an entry

or reconciliation that a refund of excessive duties, taxes, fees or interest (at the rate determined in accordance with  $\S 24.3a(c)(1)$ ) is due, a refund shall be prepared in the name of the person to whom the refund is due, as determined under paragraphs (b) and (c) of this section. \* \* For purposes of this section:

(1) Except as otherwise provided in paragraphs (a)(1)(i) through (a)(1)(iii) of this section, the refund shall include interest on the excess moneys deposited with Customs, and such interest shall accrue from the date the duties, taxes, fees or interest were deposited or, in a case in which a proper claim is filed under 19 U.S.C. 1520(d) and subpart D of Part 181 of this chapter, from the date such claim is filed, to the date of liquidation or reliquidation of the applicable entry or reconciliation. An example follows:

Example: Entry liquidates for a refund



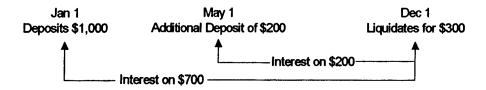
Importer is owed a refund of \$600 plus interest as follows:

The importer makes a \$1,000 initial deposit (January 1) and the entry liquidates for \$400 (December 1). Upon liquidation, the importer will be owed a refund of \$600 plus interest. The interest will accrue from the date of deposit (January 1) to the date of liquidation (December 1).

(i) If an additional deposit of duties, taxes, fees or interest was made prior to liquidation or reliquidation and if any portion of that additional deposit was in excess of the amount required to be deposited, in addition to any other interest accrued under this paragraph (a)(1), the refund also shall include

interest accrued on the excess additional deposit from the date of the additional deposit to the date of liquidation or reliquidation of the applicable entry or reconciliation. An example follows:

Example: Additional deposit made and entry liquidates for a refund



Importer is owed a refund of \$900 plus interest as follows:

The importer makes a \$1,000 initial deposit (January 1) and an additional pre-liquidation deposit of \$200 (May 1) and the entry liquidates for \$300 (December 1). Upon liquidation, the importer will be refunded \$900 plus interest. The interest accrues in two segments: (1) On the additional deposit overpayment (\$200), from the date of the additional deposit (May 1) to the date of liquidation (December 1); and (2) on the initial deposit overpayment (\$700), from the

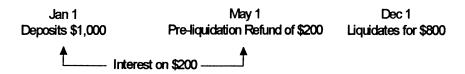
date of deposit (January 1) to the date of liquidation (December 1).

(ii) In the case of a refund of duties, taxes, fees or interest made prior to liquidation, such a refund will include only principal amounts and not any interest thereon. Interest on such principal amounts will be computed at the time of liquidation or reliquidation and shall accrue as follows:

(A) Interest shall only accrue on the amount refunded from the date the

duties, taxes, fees or interest were deposited to the date of the refund if the amount refunded is determined upon liquidation or reliquidation of the applicable entry or reconciliation to constitute the true excess amount deposited with Customs. An example follows:

Example: Pre-liquidation refund and entry liquidates for net amount collected



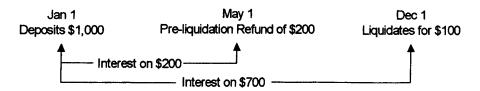
Importer is owed a refund of interest on \$200 as follows:

The importer makes a \$1,000 initial deposit (January 1) and receives a pre-liquidation refund of \$200 (May 1) and the entry liquidates for \$800 (December 1). Upon liquidation, the importer will be refunded interest on the \$200 overpayment from the

date of the initial deposit (January 1) to the date of the pre-liquidation refund (May 1).

(B) If the amount refunded is determined upon liquidation or reliquidation of the applicable entry or reconciliation to constitute less than the true excess amount deposited with Customs, in addition to any other interest accrued under this paragraph (a)(1), interest also shall accrue on the remaining excess deposit from the date the duties, taxes, fees or interest were deposited to the date of liquidation or reliquidation. An example follows:

Example: Pre-liquidation refund and entry liquidates for an additional refund



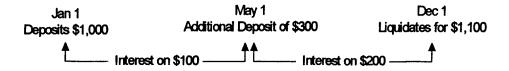
Importer is owed a refund of \$700 plus interest as follows:

The importer makes a \$1,000 initial deposit (January 1) and receives a pre-liquidation refund of \$200 (May 1) and the entry liquidates for \$100 (December 1). Upon liquidation, the importer will be refunded \$700 plus interest. The interest accrues in two segments: (1) On the pre-liquidation refund (\$200), from the date of deposit

(January 1) to the date of the pre-liquidation refund (May 1); and (2) on the remaining overpayment (\$700), from the date of deposit (January 1) to the date of liquidation (December 1).

(C) If an entry or reconciliation is determined upon liquidation or reliquidation to involve both an initial underpayment and an additional excess deposit, interest in each case shall be computed separately and the resulting amounts shall be netted for purposes of determining the final amount of interest to be reflected in the refund. An example follows:

Example: Additional deposit made and entry liquidates for a refund



Importer is owed a refund of \$200 plus or minus net interest as follows:

The importer makes a \$1,000 initial deposit on the required date (January 1) and an additional pre-liquidation deposit of \$300 (May 1) and the entry liquidates for \$1,100 (December 1). Upon liquidation, the importer will be refunded \$200 plus or minus net interest. The interest accrues in two segments: (1) Interest accrues in favor of the Government on the initial underpayment (\$100) from the date deposit was required (January 1) to the date of the additional deposit (May 1); and (2) interest accrues in favor of the importer on the overpayment (\$200) from the date of the additional deposit (May 1) to the date of liquidation (December 1).

(D) If the amount refunded or any portion thereof exceeds the amount properly refundable as determined upon liquidation or reliquidation of the applicable entry or reliquidation, the excess amount refunded shall be treated as an underpayment of duties, taxes, fees or interest on which interest shall accrue as provided in § 24.3a.

(2) A refund determined to be due upon liquidation or reliquidation, including a refund consisting only of interest that has accrued in accordance with paragraph (a)(1)(ii) of this section, shall be paid within 30 days of the date of liquidation or reliquidation of the applicable entry or reconciliation.

(3) If a refund, including any interest thereon, is not paid in full within the applicable 30-day period specified in paragraph (a)(2) of this section, the refund shall be considered delinquent thereafter and interest shall accrue on the unpaid balance by 30-day periods until the full balance is paid. However, no interest will accrue during the 30-day period in which the refund is paid.

# **PART 159—LIQUIDATION OF DUTIES**

1. The authority citation for Part 159 is revised to read as follows:

**Authority:** 19 U.S.C. 66, 1500, 1504, 1624. Subpart C also issued under 31 U.S.C. 5151.

Sections 159.4, 159.5, and 159.21 also issued under 19 U.S.C. 1315;

Section 159.6 also issued under 19 U.S.C. 1321, 1505;

Section 159.7 also issued under 19 U.S.C. 1557;

Section 159.22 also issued under 19 U.S.C. 1507;

Section 159.44 also issued under 15 U.S.C. 73, 74;

Section 159.46 also issued under 19 U.S.C. 1304;

Section 159.55 also issued under 19 U.S.C. 1558;

Section 159.57 also issued under 19 U.S.C. 1516;

# §§ 159.4, 159.6, 159.7, 159.21, 159.22, 159.44, 159.46, 159.55, 159.57 [Amended]

- 2. The parenthetical authority citations at the end of §§ 159.4, 159.5, 159.6, 159.7, 159.21, 159.22, 159.44, 159.46, 159.55, and 159.57 are removed.
- 3. In § 159.6:
- a. The first sentence of paragraph (a) is amended by removing the words "and taxes" the first time they appear and

adding, in their place, the words "taxes, and interest";

- b. The introductory text of paragraph (b) is amended by removing the words "and taxes" wherever they appear and adding, in their place, the words "taxes, and interest":
- c. Paragraph (c) is amended by removing the words "and taxes assessed in the liquidation" and adding, in their place, the words "taxes, and interest assessed in the liquidation" and by removing the words "and taxes assessed in the reliquidation" and adding, in their place, the words "taxes, and interest assessed in the reliquidation"; and
- d. In paragraph (d), the paragraph heading and the paragraph text are amended by adding "and interest" after "taxes".

## PART 174—PROTESTS

1. The authority citation for Part 174 continues to read as follows:

Authority: 19 U.S.C. 66, 1514, 1515, 1624.

# §174.11 [Amended]

2. In § 174.11, paragraph (c) is amended by adding ", including the accrual of interest," after "character".

## §174.12 [Amended]

3. In § 174.12, paragraph (a)(2) is amended by adding ", or receiving a refund of," after "paying".

Approved: July 28, 1999.

# Raymond W. Kelly,

Commissioner of Customs.

#### Dennis M. O'Connell,

Acting Deputy Assistant Secretary of the Treasury.

[FR Doc. 99–26882 Filed 10–19–99; 8:45 am] BILLING CODE 4820–02–P

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 3, 5, 10, 20, 50, 56, 58, 207, 310, 312, 316, 600, 601, 607, 610, 640, and 660

[Docket No. 98N-0144]

RIN 0910-AB29

Biological Products Regulated Under Section 351 of the Public Health Service Act; Implementation of Biologics License; Elimination of Establishment License and Product License

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the biologics regulations to eliminate references to establishment licenses and product licenses for all products regulated under the Public Health Service Act (the PHS Act). In lieu of filing an establishment license application (ELA) and product license application (PLA) in order to market a biological product in interstate commerce, a manufacturer will file a single biologics license application (BLA) with the agency. Upon approval of the BLA, a manufacturer will receive a biologics license to market the product in interstate commerce. This action is part of FDA's continuing effort to achieve the objectives of the President's "Reinventing Government" initiatives and is intended to reduce unnecessary burdens for industry without diminishing public health protection. This action implements certain sections of the FDA Modernization Act of 1997 (FDAMA).

**DATES:** *Effective date*: The regulation is effective December 20, 1999.

Compliance Date: Submit all applications with the Form FDA 356h by December 20, 1999, and submit any application for licensure as a BLA by October 20, 2000.

FOR FURTHER INFORMATION CONTACT: Robert A. Yetter, Center for Biologics Evaluation and Research (CBER) (HFM– 10), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827– 0373.

## SUPPLEMENTARY INFORMATION:

# I. Background

In the Federal Register of July 31, 1998 (63 FR 40858), FDA proposed to amend the biologics and other drug regulations to eliminate references to the PLA and ELA and to replace such references with the BLA. FDA provided 75 days for comments on the proposed rule. FDA held a public meeting, announced in the Federal Register of August 11, 1998 (63 FR 42773), on September 2, 1998, to discuss the BLA/ biologics license scheme. FDA also invited the submission of written comments to the docket at the public meeting. The transcript of the public meeting and written comments to the proposed rule are on file in the Dockets Management Branch (HFA-305), 5630 Fishers Lane, rm. 1061, Rockville, MD

Prior to the issuance of the proposed rule, FDA had already reviewed its process of licensing biological products and had taken a number of actions to reduce the regulatory burdens imposed

by the licensing process and to make the licensing process more consistent with the process for the approval of new drugs. In the Federal Register of May 14, 1996 (61 FR 24227), FDA issued a final rule to amend the biologics regulations by eliminating the ELA requirement for the following specified biotechnology and synthetic biological products licensed under section 351 of the PHS Act (42 U.S.C. 262 et seq.): (1) Therapeutic deoxyribonucleic acid (DNA) plasmid products; (2) therapeutic synthetic peptide products of 40 or fewer amino acids; (3) monoclonal antibody products for in vivo use; and (4) therapeutic recombinant DNAderived products. That provision applied only to those products that FDA determined under principles articulated in the "Intercenter Agreement Between the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research" (effective on October 31, 1991) to be subject to licensure under section 351 of the PHS Act. Thus, upon approval, manufacturers of the specified biotechnology and synthetic biological products received a single biologics license instead of a product license and an establishment license (see § 601.2(c) (21 CFR 601.2(c))).

In the **Federal Register** of July 8, 1997 (62 FR 36558), FDA announced the availability of a revised Form FDA 356h entitled "Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use." Form FDA 356h was revised as a "Reinventing Government" initiative to harmonize application procedures between CBER and the Center for Drug Evaluation and Research (CDER) as outlined in the President's November 1995 National Performance Review Report entitled "Reinventing the Regulation of Drugs Made From Biotechnology." In the notice, FDA advised that applicants for biologics licenses for products specified in § 601.2(c) as well as autologous somatic cell therapy products could begin to use Form FDA 356h immediately and were required to do so beginning January 8, 1998. FDA advised applicants for licenses for other biological products that the agency would announce in the future when they can voluntarily begin to use and will be required to use Form FDA 356h. Upon approval of a BLA submitted on Form FDA 356h, FDA will issue a single biologics license. FDA believes that this licensing procedure will greatly simplify the application process, harmonize application procedures with those of CDER, and reduce industry and agency paperwork burdens. As a consequence of this final