PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR. 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9F, Airspace Designations and Reporting Points, dated September 10, 1998, and effective September 16, 1998, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ACE MO E5 Bolivar MO [New]

Bolivar Municipal Airport, MO
(Lat. 37°35′43″ N., long. 93°20′52″ W.)

That airspace extending upward from 700 feet above the surface within a 6.3-mile radius of the Bolivar Municipal Airport.

* * * * *

Issued in Kansas City, MO, on September 2, 1998.

Christopher R. Blum,

Acting Manager, Air Traffic Division, Central Region.

[FR Doc. 98–25746 Filed 9–28–98; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Parts 162, 171 and 191

RIN 1515–AC21

Penalties for False Drawback Claims

AGENCY: Customs Service, Department of the Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document proposes to amend the Customs Regulations to set forth the procedures to be followed when false drawback claims are filed and penalties are thereby incurred. The proposed regulatory changes would implement section 622 of the Customs modernization provisions of the North American Free Trade Agreement Implementation Act. These new provisions track, to the greatest extent possible, the procedures that have been set forth for section 592 of the Tariff Act of 1930, as amended (19 U.S.C. 1592). This document also sets forth proposed mitigation guidelines that Customs would follow in arriving at a just and reasonable assessment and disposition of liabilities when false drawback claims are filed and penalties are incurred. Finally, the document proposes to amend the Customs Regulations in order to provide more specificity regarding the grounds and procedures for removal of a participant from the drawback compliance program.

DATES: Comments must be received on or before November 30, 1998.

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, NW, Washington, DC 20229. Comments submitted may be inspected at the Regulations Branch, Office of Regulations and Rulings, U.S. Customs Service, 1300 Pennsylvania Avenue, NW, 3rd Floor, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Charles Ressin, Penalties Branch, Office of Regulations and Rulings, 202–927–2264.

SUPPLEMENTARY INFORMATION:

Background

This document proposes to amend the Customs Regulations to implement section 622 of Title VI of the North American Free Trade Agreement Implementation Act (Pub. L. 103–182). Title VI of the North American Free Trade Agreement Implementation Act is popularly known as the Customs Modernization Act. Paragraph (a) of section 622 amended the Tariff Act of 1930, as amended, by adding section 593A, which prohibits the filing of false (fraudulent or negligent) drawback claims and prescribes the actions that Customs may take, including the assessment of monetary penalties, if such claims are filed (gross negligence is not separately set forth as a level of culpability in the new statutory provision). New section 593A was codified as section 1593a of Title 19 of the United States Code (19 U.S.C. 1593a, hereinafter ''the statute'').

As in the case of penalties under section 592 of the Tariff Act of 1930, as amended (19 U.S.C. 1592), specific procedures and other requirements are set forth in the statute for prepenalty notices and penalty claims, the former not being required by the statute if the penalty is $1,000 or less. The statute provides that approval of Customs Headquarters is required if a prepenalty notice alleging fraud is contemplated. The statute also further provides for the applicability of section 618 of the Tariff Act of 1930, as amended (19 U.S.C. 1618), which authorizes the administrative remission or mitigation of penalties. Written decisions, setting forth a final determination and findings of fact and conclusions of law upon which that determination was based, are also mandated by the statute.

Rather than setting forth specific penalty amounts, the statute provides for the assessment of monetary penalties in amounts not to exceed a specific percentage of the actual or potential loss of revenue, with the applicable percentage depending on the level of culpability, whether there have been prior violations involving the same issue, and whether the violator is a participant in the Customs drawback compliance program (the statute provides for the establishment of a drawback compliance program, and regulatory provisions relating to the operation of that program were adopted as part of the amendments to the Customs Regulations regarding drawback published in the **Federal Register** as T.D. 98–16 on March 5, 1998, 63 FR 10970). For purposes of applying the monetary penalties prescribed in the statute, Customs proposes in this document to define loss of revenue with reference to the amount of drawback that is claimed and to which the claimant is not entitled.

The statute further provides for limited penalty assessment for filing a false drawback claim if there is a prior disclosure of the violation. As in cases brought under section 592, the limited penalty assessment would be applicable only in those instances in which the circumstances of the violation are disclosed before, or without knowledge of the commencement of, a formal investigation. In this context, this document should be read in conjunction with the notice of proposed rulemaking regarding prior disclosure that was published in the **Federal Register** on September 26, 1996 (61 FR 50459).

The statute provides for penalties, or notices of violation in lieu of penalties, as set forth below in cases involving negligent violations (under the statute, a repetitive violation is one which involves the same issue as a prior violation): 1. If the violator is not a participant in the drawback compliance program, Customs shall assess monetary penalties in amounts not to exceed the following:

a. 20 percent of the loss of revenue for the first violation;

b. 50 percent of the loss of revenue for the first repetitive violation; and

c. The loss of revenue in the case of a second and each subsequent repetitive violation.

2. If the violator is a participant in the drawback compliance program and is generally in compliance with the provisions thereof, the following actions shall be taken by Customs:

a. For a first violation and for any other violation that is not repetitive or that involves the same issue as a prior violation but does not occur within three years from the date of that prior violation, a notice of violation (warning letter) shall be issued;

b. For the first violation that is repetitive and that occurs within three years from the date of the violation of which it is repetitive, a monetary penalty of up to 20 percent of the loss of revenue shall be assessed;

c. For the second violation that is repetitive and that occurs within three years from the date of the first of two violations of which it is repetitive, a monetary penalty of up to 50 percent of the loss of revenue shall be assessed; and

d. For a third and each subsequent violation that is repetitive and that occurs within three years from the date of the first of three or more violations of which it is repetitive, a monetary penalty not to exceed the loss of revenue shall be assessed.

In the case of a fraudulent violation, the statute makes no distinction between drawback compliance program participants and those who do not participate in the program: a fraudulent violation gives rise to a monetary penalty in an amount not exceeding three times the loss of revenue or, if there has been a prior disclosure regarding the fraudulent violation, in an amount not exceeding the loss of revenue.

If there has been a valid prior disclosure regarding a negligent violation, drawback compliance program participants and those who do not participate in that program are also treated the same: the violator is subject to a monetary penalty that may not exceed an amount equal to the interest computed on the basis of the prevailing rate of interest applied under 26 U.S.C. 6621 on the amount of actual revenue of which the United States is or may be deprived during the period from the date of overpayment of the claim to the date of tender of the overpaid amount.

In order to obtain the benefits of prior disclosure in both fraud and negligence cases, tender of the amount of the overpayment is required either at the time of disclosure or within 30 days (or such longer period as Customs may provide) after Customs gives notice of its calculation of the amount of the overpayment.

Paragraph (b) of section 622 of the Customs Modernization Act provides that the provisions of the statute shall apply only to drawback claims filed on and after Customs implements nationwide an automated drawback selectivity program, and mandates the publication in the Customs Bulletin of the effective date of the selectivity program.

The proposed amendments set forth in this document to implement the statute involve changes to the penalty procedure provisions within parts 162 and 171 of the regulations and the addition of a new appendix D to part 171 to set forth guidelines for the imposition and mitigation of monetary penalties incurred under the statute. To the greatest extent possible, and except where the statute expressly mandates a different approach, the regulatory amendments set forth in this document are modeled on the section 592 regulatory provisions and thus, among other things, reflect the definitions of ''fraud'' and ''negligence'' (which includes gross negligence) that are intended to be applied in cases brought under section 592 (*see* Senate Report 103–189 at pages 73–74). As noted above, these proposed regulations, if adopted as a final rule, will not be effective until Customs implements an automated drawback selectivity program.

Finally, with regard to the final amendments to the Customs Regulations regarding drawback published as T.D. 98–16 as mentioned above, Customs notes that the provisions regarding the operation of the drawback compliance program (set forth as subpart S within part 191) include, in § 191.194 (e) and (f), procedures regarding the revocation of certification for participation in the program. However, contrary to the approach taken elsewhere in the Customs Regulations in the context of a revocation or removal of a privilege, those drawback compliance program provisions do not include specific grounds for such action. Moreover, those paragraph (e) and (f) texts only refer to proposed revocation actions (with a delayed effective date following notice of the proposed revocation). Thus, no provision exists in those regulatory texts for a revocation with immediate effect when the basis for the revocation involves willfulness on the part of the program participant or when public health, interest, or safety requires immediate revocation, notwithstanding the fact that such immediate action may be necessary and would be consistent with the license revocation principles enshrined in the Administrative Procedure Act (see 5 U.S.C. 558(c)). This document proposes to revise § 191.194 (e) and (f) in order to address the above points and in order to otherwise improve the organization of, and procedures reflected in, those texts. In addition, the proposed text revisions refer to ''removal'' (rather than ''revocation'') of certification in order to reflect statutory terminology (see 19 U.S.C. 1593a(f)(1)).

Comments

Before adopting these proposed amendments, consideration will be given to any written comments timely submitted to Customs. Comments submitted will be available for public inspection in accordance with the Freedom of Information Act (5 U.S.C. 552), § 1.4, Treasury Regulations (31 CFR 1.4), and § 103.11(b), 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.

Regulatory Flexibility Act and Executive Order 12866

Insofar as the proposed regulations closely follow legislative direction, pursuant to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601, *et seq.*), it is certified that the proposed amendments, if adopted, will not have a significant economic impact on a substantial number of small entities. Accordingly, the amendments are not subject to the regulatory analysis requirements of 5 U.S.C. 603 and 604. This document does not meet the criteria for a ''significant regulatory action'' as specified in E.O. 12866.

List of Subjects

19 CFR Part 162

Customs duties and inspection; Law enforcement; Penalties; Seizures and forfeitures.

19 CFR Part 171

Administrative practice and procedure; Customs duties and inspection; Law enforcement; Penalties; Seizures and forfeitures.

19 CFR Part 191

Administrative practice and procedure; Customs duties and inspection; Drawback.

Proposed Amendments to The Regulations

For the reasons set forth above, it is proposed to amend parts 162, 171 and 191 of the Customs Regulations (19 CFR parts 162, 171 and 191) as follows:

PART 162—RECORDKEEPING, INSPECTION, SEARCH, AND SEIZURE

1. The general authority citation for part 162 is revised to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1592, 1593a, 1624.

* * * * *

2. In § 162.71, paragraphs (b) through (e) are redesignated as paragraphs (d) through (g) and the heading for paragraph (a) is revised, and new paragraphs (b) and (c) are added, to read as follows:

§ 162.71 Definitions.

* * * * *

(a) *Loss of duties under section 592.* * * *

(b) *Loss of revenue under section 593A.* When used in § 162.73a, the term *loss of revenue* means the amount of drawback that is claimed and to which the claimant is not entitled and includes both actual and potential loss of revenue.

(1) *Actual loss of revenue.* When used in §§ 162.73a, 162.74(h), 162.77a and 162.79b, the term *actual loss of revenue* means the amount of drawback that is claimed and has been paid to the claimant and to which the claimant is not entitled.

(2) *Potential loss of revenue.* When used in § 162.77a, the term *potential loss of revenue* means the amount of drawback that is claimed and has not been paid to the claimant and to which the claimant is not entitled.

(c) *Repetitive violation.* When used in § 162.73a to describe a violation, *repetitive* has reference to a violation by a person that involves the same issue as a prior violation by that person.

* * * * *

3. A new § 162.73a is added to read as follows:

§ 162.73a Penalties under section 593A, Tariff Act of 1930, as amended.

(a) *Maximum penalty without prior disclosure for a drawback compliance program nonparticipant.* If the person concerned has not made a prior disclosure as provided in § 162.74 and has not been certified as a participant in the drawback compliance program under part 191 of this chapter, the monetary penalty under section 593A, Tariff Act of 1930, as amended (19 U.S.C. 1593a), shall not exceed:

(1) For fraudulent violations, three times the loss of revenue; and

(2) For negligent violations, (i) 20 percent of the loss of revenue for the first violation,

(ii) 50 percent of the loss of revenue for the first repetitive violation, or

(iii) One times the loss of revenue for the second and each subsequent repetitive violation.

(b) *Maximum penalty without prior disclosure for a drawback compliance program participant*—(1) *General.* If the person concerned has not made a prior disclosure as provided in § 162.74 and has been certified as a participant in, and is generally in compliance with the procedures and requirements of, the drawback compliance program provided for in part 191 of this chapter, the monetary penalty or other sanction under section 593A, Tariff Act of 1930, as amended (19 U.S.C. 1593a), shall not exceed:

(i) For fraudulent violations, three times the loss of revenue; and

(ii) For negligent violations,

(A) Issuance of a written notice of a violation (warning letter) for the first violation and for any other violation that is not repetitive or that is repetitive but does not occur within three years from the date of the violation of which it is repetitive,

(B) 20 percent of the loss of revenue for the first repetitive violation that occurs within three years from the date of the violation of which it is repetitive,

(C) 50 percent of the loss of revenue for the second repetitive violation that occurs within three years from the date of the first of two violations of which it is repetitive, or

(D) One times the loss of revenue for the third and each subsequent repetitive violation that occurs within three years from the date of the first of three or more violations of which it is repetitive.

(2) *Notice of violation and response thereto.* (i) The notice issued by Customs under paragraph (b)(1)(ii)(A) of this section shall:

(A) State that the person concerned has violated section 593A;

(B) Explain the nature of the violation; and

(C) Warn the person concerned that future violations of section 593A may result in the imposition of monetary penalties. The notice shall also warn the person concerned that repetitive violations may result in removal of certification under the drawback compliance program provided for in part 191 of this chapter until the person takes corrective action that is satisfactory to Customs.

(ii) Within 30 days from the date of mailing of the notice issued under paragraph (b)(1)(ii)(A) of this section, the person concerned shall notify Customs in writing of the steps that have been taken to prevent a recurrence of the violation.

(c) *Maximum penalty with prior disclosure.* If the person concerned has made a prior disclosure as provided in § 162.74, whether or not such person has been certified as a participant in the drawback compliance program under part 191 of this chapter, the monetary penalty under section 593A, Tariff Act of 1930, as amended (19 U.S.C. 1593a), shall not exceed:

(1) For fraudulent violations, one times the loss of revenue; and

(2) For negligent violations, an amount equal to the interest accruing on the actual loss of revenue during the period from the date of overpayment of the claim to the date on which the person concerned tenders the amount of the overpayment based on the prevailing rate of interest under 26 U.S.C. 6621.

4. A new § 162.77a is added to read as follows:

§ 162.77a Prepenalty notice for violation of section 593A, Tariff Act of 1930, as amended.

(a) *When required.* If the appropriate Customs field officer has reasonable cause to believe that a violation of section 593A, Tariff Act of 1930, as amended (19 U.S.C. 1593a) has occurred, and determines that further proceedings are warranted, the officer shall issue to the person concerned a notice of intent to issue a claim for a monetary penalty.

(b) *Contents*—(1) *Facts of violation.* The prepenalty notice shall:

(i) Identify the drawback claim;

(ii) Set forth the details relating to the seeking, inducing, or affecting, or the attempted seeking, inducing, or affecting, or the aiding or procuring of, the drawback claim;

(iii) Specify all laws and regulations allegedly violated;

(iv) Disclose all the material facts which establish the alleged violation;

(v) State whether the alleged violation occurred as a result of fraud or negligence; and

(vi) State the estimated actual or potential loss of revenue due to the drawback claim and, taking into account all circumstances, the amount of the proposed monetary penalty.

(2) *Right to make presentations.* The prepenalty notice also shall inform the person of his right to make an oral and a written presentation within 30 days of mailing of the notice (or such shorter period as may be prescribed under § 162.78) as to why a claim for a monetary penalty should not be issued or, if issued, why it should be in a lesser amount than proposed.

(c) *Exceptions.* A prepenalty notice shall not be issued for a violation of 19 U.S.C. 1593a if the amount of the proposed monetary penalty is $1,000 or less.

(d) *Prior approval.* If an alleged violation of 19 U.S.C. 1593a occurred as a result of fraud, a prepenalty notice shall not be issued without prior approval by Customs Headquarters.

§ 162.79a [Amended]

5. Section 162.79a is amended by removing the references ''§ 162.76(b)(1) or § 162.77(b)(1)'' and adding, in their place, ''§ 162.76(b)(1), § 162.77(b)(1) or § 162.77a(b)(1) and (b)(2)''.

6. Section 162.79b is revised to read as follows:

§ 162.79b Recovery of actual loss of duties or revenue.

Whether or not a monetary penalty is assessed under this subpart, the appropriate Customs field officer shall require the deposit of any actual loss of duties resulting from a violation of section 592, Tariff Act of 1930, as amended (19 U.S.C. 1592) or any actual loss of revenue resulting from a violation of section 593A, Tariff Act of 1930, as amended (19 U.S.C. 1593a), notwithstanding that the liquidation of the entry to which the loss is attributable has become final. If a person is liable for the payment of actual loss of duties or actual loss of revenue in any case in which a monetary penalty is not assessed or a written notification of claim of monetary penalty is not issued, the port director shall issue a written notice to the person of the liability for the actual loss of duties or actual loss of revenue. The notice shall identify the merchandise and entries involved, state the loss of duties or revenue and how it was calculated, and require the person to deposit or arrange for payment of the duties or revenue within 30 days from the date of the notice. Any determination of actual loss of duties or actual loss of revenue under this section is subject to review upon written application to the Commissioner of Customs.

PART 171—FINES, PENALTIES, AND FORFEITURES

1. The authority citation for part 171 is revised to read in part as follows:

Authority: 19 U.S.C. 66, 1592, 1593a, 1618, 1624. * * *

2. Section 171.21 is revised to read as follows:

§ 171.21 Written decisions.

If a petition for relief relates to a violation of section 592, 593A or 641, Tariff Act of 1930, as amended (19 U.S.C. 1592, 19 U.S.C. 1593a or 19 U.S.C. 1641), the petitioner shall be provided with a written statement setting forth the decision on the matter and the findings of fact and conclusions of law upon which the decision is based.

3. Part 171 is amended by adding a new Appendix D to read as follows:

Appendix D To Part 171—Guidelines for the Imposition and Mitigation of Penalties for Violations of 19 U.S.C. 1593A

A monetary penalty incurred under section 593A, Tariff Act of 1930, as amended (19 U.S.C. 1593a; hereinafter referred to as section 593A), may be remitted or mitigated under section 618, Tariff Act of 1930, as amended (19 U.S.C. 1618; hereinafter referred to as section 618), if it is determined that there exist such mitigating circumstances as to justify remission or mitigation. The guidelines below will be used by Customs in arriving at a just and reasonable assessment and disposition of liabilities arising under section 593A within the stated limitations. It is intended that these guidelines shall be applied by Customs officers in prepenalty proceedings, in determining the monetary penalty assessed in the penalty notice, and in arriving at a final penalty disposition. The assessed or mitigated penalty amount set forth in Customs administrative disposition determined in accordance with these guidelines does not limit the penalty amount which the Government may seek in bringing a civil enforcement action pursuant to 19 U.S.C. 1593a(i).

(A) Violations of Section 593A

A violation of section 593A occurs when a person, through fraud or negligence, seeks, induces, or affects, or attempts to seek, induce, or affect, the payment or credit to that person or others of any drawback claim by means of any document, written or oral statement, or electronically transmitted data or information, or act which is material and false, or any omission which is material, or aids or abets any other person in the foregoing violation. There is no violation if the falsity is due solely to clerical error or mistake of fact unless the error or mistake is part of a pattern of negligent conduct. Also, the mere nonintentional repetition by an electronic system of an initial clerical error shall not constitute a pattern of negligent conduct. Nevertheless, if Customs has drawn the person's attention to the nonintentional repetition by an electronic system of an initial clerical error, subsequent failure to correct the error could constitute a violation of section 593A.

(B) Degrees of Culpability

There are two degrees of culpability under section 593A: negligence and fraud.

(1) *Negligence.* A violation is determined to be negligent if it results from an act or acts (of commission or omission) done with actual knowledge of, or wanton disregard for, the relevant facts and with indifference to, or disregard for, the offender's obligations under the statute or done through the failure to exercise the degree of reasonable care and competence expected from a person in the same circumstances in ascertaining the facts or in drawing inferences therefrom, in ascertaining the offender's obligations under the statute, or in communicating information so that it may be understood by the recipient. As a general rule, a violation is determined to be negligent if it results from the offender's failure to exercise reasonable care and competence to ensure that a statement made is correct.

(2) *Fraud.* A violation is determined to be fraudulent if the material false statement, omission or act in connection with the transaction was committed (or omitted) knowingly, i.e., was done voluntarily and intentionally, as established by clear and convincing evidence.

(C) Assessment of Penalties

(1) *Issuance of Prepenalty Notice.* As provided in § 162.77a of the Customs Regulations (19 CFR 162.77a), if Customs has reasonable cause to believe that a violation of section 593A has occurred and determines that further proceedings are warranted, a notice of intent to issue a claim for a monetary penalty shall be issued to the person concerned. In issuing such prepenalty notice, the appropriate Customs field officer shall make a tentative determination of the degree of culpability and the amount of the proposed claim. A prepenalty notice shall not be issued if the claim does not exceed $1,000.

(2) *Issuance of Penalty Notice.* After considering representations, if any, made by the person concerned pursuant to the notice issued under paragraph (C)(1), the appropriate Customs field officer shall determine whether any violation described in section (A) has occurred. If a notice was issued under paragraph (C)(1) and the appropriate Customs field officer determines that there was no violation, Customs shall promptly issue a written statement of the determination to the person to whom the notice was sent. If the appropriate Customs field officer determines that there was a violation, Customs shall issue a written penalty claim to the person concerned. The written penalty claim shall specify all changes in the information provided in the prepenalty notice issued under paragraph (C)(1). The person to whom the penalty notice is issued shall have a reasonable opportunity under section 618 to make representations, both oral and written, seeking remission or mitigation of the monetary penalty. At the conclusion of any proceeding under section 618, Customs shall provide to the person concerned a written statement which sets forth the final determination and the findings of fact and conclusions of law on which such determination is based.

(D) Maximum Penalties

(1) *Fraud.* In the case of a fraudulent violation of section 593A, the monetary penalty shall be in an amount not to exceed 3 times the actual or potential loss of revenue.

(2) *Negligence.*

(a) *In General.* In the case of a negligent violation of section 593A, the monetary penalty shall be in an amount not to exceed 20 percent of the actual or potential loss of revenue for the first violation.

(b) *Repetitive Violations.* For the first negligent violation that is repetitive (i.e., involves the same issue and the same violator), the penalty shall be in an amount not to exceed 50 percent of the actual or potential loss of revenue. The penalty for a second and each subsequent repetitive negligent violation shall be in an amount not to exceed the actual or potential loss of revenue.

(3) *Prior Disclosure.*

(a) *In General.* Subject to paragraph (D)(3)(b), if the person concerned discloses the circumstances of a violation of section 593A before, or without knowledge of the commencement of, a formal investigation of such violation, the monetary penalty assessed under this Appendix may not exceed:

(i) In the case of fraud, an amount equal to the actual or potential revenue of which the United States is or may be deprived as a result of overpayment of the claim; or

(ii) If the violation resulted from negligence, an amount equal to the interest computed on the basis of the prevailing rate of interest applied under 26 U.S.C. 6621 on the amount of actual revenue of which the United States is or may be deprived during the period that begins on the date of overpayment of the claim and ends on the date on which the person concerned tenders the amount of the overpayment.

(b) *Condition Affecting Penalty Limitations.* The limitations in paragraph (D)(3)(a) on the amount of the monetary penalty to be assessed apply only if the person concerned tenders the amount of the overpayment made on the claim either at the time of the disclosure or within 30 days (or such longer period as Customs may provide) from the date of notice by Customs of its calculation of the amount of overpayment.

(c) *Burden of Proof.* The person asserting lack of knowledge of the commencement of a formal investigation has the burden of proof in establishing such lack of knowledge.

(d) *Commencement of Investigation.* For purposes of this Appendix, a formal investigation of a violation is considered to be commenced with regard to the disclosing party, and with regard to the disclosed information, on the date recorded in writing by Customs as the date on which facts and circumstances were discovered which caused Customs to believe that a possibility of a violation of section 593A existed.

(e) *Exclusivity.* Penalty claims under section D shall be the exclusive civil remedy for any drawback-related violation of section 593A.

(E) Deprivation of Lawful Revenue

Notwithstanding section 514, Tariff Act of 1930, as amended (19 U.S.C. 1514), if the United States has been deprived of lawful duties and taxes resulting from a violation of section 593A, Customs shall require that such duties and taxes be restored whether or not a monetary penalty is assessed.

(F) Final Disposition of Penalty Cases When the Drawback Claimant Is Not a Certified Participant in the Drawback Compliance Program

(1) *In General.* Customs shall consider all information in the petition and all available evidence, taking into account any mitigating, aggravating, and extraordinary factors, in determining the final assessed penalty. All factors considered should be stated in the decision.

(2) *Penalty Disposition When There Has Been No Prior Disclosure.*

(a) *Nonrepetitive Negligent Violation.* The final penalty disposition shall be in an amount ranging from a minimum of 10 percent of the actual or potential loss of revenue to a maximum of 20 percent of the actual or potential loss of revenue.

(b) *Repetitive Negligent Violation.*

(i) *First Repetitive Negligent Violation.* The final penalty disposition shall be in an amount ranging from a minimum of 25 percent of the actual or potential loss of revenue to a maximum of 50 percent of the actual or potential loss of revenue.

(ii) *Second and Each Subsequent Repetitive Negligent Violation.* The final penalty disposition shall be in an amount ranging from a minimum of 50 percent of the actual or potential loss of revenue to a maximum of 100 percent of the actual or potential loss of revenue.

(c) *Fraudulent Violation.* The final penalty disposition shall be in an amount ranging from a minimum of 1.5 times the actual or potential loss of revenue to a maximum of 3 times the actual or potential loss of revenue.

(3) *Penalty Disposition When There Has Been a Prior Disclosure.*

(a) *Negligent Violation.* The final penalty disposition shall be in an amount equal to the interest determined in accordance with paragraph (D)(3)(a)(ii).

(b) *Fraudulent Violation.* The final penalty disposition shall be in an amount equal to 100 percent of the actual or potential loss of revenue.

(4) *Mitigating Factors.* The following factors shall be considered in mitigation of the proposed or assessed penalty claim or final penalty amount, provided that the case record sufficiently establishes their existence. The list is not exclusive.

(a) *Contributory Customs Error.* This factor includes misleading or erroneous advice given by a Customs official in writing to the alleged violator, but this factor may be applied in such a case only if it appears that the alleged violator reasonably relied upon the written information and the alleged violator fully and accurately informed Customs of all relevant facts. The concept of comparative negligence may be utilized in determining the weight to be assigned to this factor. If the Customs error contributed to the violation, but the alleged violator is also culpable, the Customs error is to be considered as a mitigating factor. If it is determined that the Customs error was the sole cause of the violation, the proposed or assessed penalty is to be cancelled.

(b) *Cooperation with the Investigation.* To obtain the benefits of this factor, the alleged violator must exhibit cooperation beyond that expected from a person under investigation for a Customs violation. An example of the cooperation contemplated includes assisting Customs officers to an unusual degree in auditing the books and records of the alleged violator (e.g., incurring extraordinary expenses in providing computer runs solely for submission to Customs to assist the agency in cases involving an unusually large number of entries and/or complex issues). Another example consists of assisting Customs in obtaining additional information relating to the subject violation or other violations. Merely providing the books and records of the alleged violator may not be considered cooperation justifying mitigation inasmuch as Customs has the right to examine an importer's books and records pursuant to 19 U.S.C. 1508–1509.

(c) *Immediate Remedial Action.* This factor includes the payment of the actual loss of revenue prior to the issuance of a penalty notice and within 30 days after Customs notifies the alleged violator of the actual loss of revenue attributable to the violation. In appropriate cases, where the alleged violator provides evidence that, immediately after learning of the violation, substantial remedial action was taken to correct organizational or procedural defects, immediate remedial action may be granted as a mitigating factor. Customs encourages immediate remedial action to ensure against future incidents of non-compliance.

(d) *Prior Good Record.* Prior good record is a factor only if the alleged violator is able to demonstrate a consistent pattern of filing drawback claims without violation of section 593A, or any other statute prohibiting the making or filing of a false statement or document in connection with a drawback claim. This factor will not be considered in alleged fraudulent violations of section 593A.

(e) *Inability to Pay the Customs Penalty.* The party claiming the existence of this factor must present documentary evidence in support thereof, including copies of income tax returns for the previous 3 years and an audited financial statement for the most recent fiscal quarter. In certain cases, Customs may waive the production of an audited financial statement or may request alternative or additional financial data in order to facilitate an analysis of a claim of inability to pay (e.g., examination of the financial records of a foreign entity related to the U.S. company claiming inability to pay). In addition, the alleged violator must present information reflecting ownership and related domestic and foreign parties and must provide information reflecting its current financial condition, including books and records of account, bank statements, other tax records (for example, sales tax returns) and a list of assets with current values; if the alleged violator is a closely held corporation, similar current financial information must be provided on the shareholders, wherever they are located.

(f) *Customs Knowledge.* This factor may be used in non-fraud cases if it is determined that Customs had actual knowledge of a violation and failed, without justification, to inform the violator so that it could have taken earlier remedial action. This factor shall not be applicable when a substantial delay in the investigation is attributable to the alleged violator.

(5) *Aggravating Factors.* Certain factors may be determined to be aggravating factors in calculating the amount of the proposed or assessed penalty claim or the amount of the

final administrative penalty. The presence of one or more aggravating factors may not be used to raise the level of culpability attributable to the alleged violations, but may be used to offset the presence of mitigating factors. The following factors shall be considered ''aggravating factors'', provided that the case record sufficiently establishes their existence. The list is not exclusive.

(a) Obstructing an investigation or audit.

(b) Withholding evidence.

(c) Providing misleading information concerning the violation.

(d) Prior substantive violations of section 593A for which a final administrative finding of culpability has been made.

(e) Failure to comply with a Customs summons or lawful demand for records.

(G) Drawback Compliance Program Participants

(1) *In General.* Special alternative procedures and penalty assessment standards apply in the case of negligent violations of section 593A committed by persons who are certified as participants in the Customs drawback compliance program and who are generally in compliance with the procedures and requirements of that program. Provisions regarding the operation of the drawback compliance program are set forth in part 191 of the Customs Regulations (19 CFR part 191).

(2) *Alternatives to Penalties.* When a participant described in paragraph (G)(1) commits a violation of section 593A, in the absence of fraud or repeated violations and in lieu of a monetary penalty, Customs shall issue a written notice of the violation (warning letter).

(a) *Contents of Notice.* The notice shall:

(i) State that the person has violated section 593A;

(ii) Explain the nature of the violation; and

(iii) Warn the person that future violations of section 593A may result in the imposition of monetary penalties and that repetitive violations may result in removal of certification under the drawback compliance program until the person takes corrective action that is satisfactory to Customs.

(b) *Response to Notice.* Within 30 days from the date of mailing of the written notice, the person shall notify Customs in writing of the steps that have been taken to prevent a recurrence of the violation. If the person fails to provide such notification in a timely manner, any penalty assessed for a repetitive violation under paragraph (G)(3) shall not be subject to mitigation under this Appendix.

(3) *Repetitive Violations.*

(a) *In General.* A person who has been issued a written notice under paragraph (G)(2) and who subsequently commits a negligent violation that is repetitive (i.e., involves the same issue), and any other person who is a participant described in paragraph (G)(1) and who commits a repetitive negligent violation, is subject to one of the following monetary penalties:

(i) An amount not to exceed 20 percent of the loss of revenue for the first repetitive violation that occurs within three years from the date of the violation of which it is repetitive;

(ii) An amount not to exceed 50 percent of the loss of revenue for the second repetitive violation that occurs within three years from the date of the first of two violations of which it is repetitive; and

(iii) An amount not to exceed 100 percent of the loss of revenue for the third and each subsequent repetitive violation that occurs within three years from the date of the first of three or more violations of which it is repetitive.

(b) *Repetitive Violations Outside 3-year Period.* If a participant described in paragraph (G)(1) commits a negligent violation that is repetitive but that did not occur within 3 years of the violation of which it is repetitive, the new violation shall be treated as a first violation for which a written notice shall be issued in accordance with paragraph (G)(2), and each repetitive violation subsequent thereto that occurs within any 3-year period described in paragraph (G)(3)(a) shall result in the assessment of the applicable monetary penalty prescribed in that paragraph.

(4) *Final Penalty Disposition When There Has Been No Prior Disclosure.*

(a) *In General.* Customs shall consider all information in the petition and all available evidence, taking into account any mitigating factors (see paragraph (F)(4)), aggravating factors (see paragraph (F)(5)), and extraordinary factors in determining the final assessed penalty. All factors considered should be stated in the decision.

(b) *First Repetitive Negligent Violation Within 3 Years of Violation Handled Under Paragraph (G)(2).* The final penalty disposition shall be in an amount ranging from a minimum of 10 percent of the loss of revenue to a maximum of 20 percent of the loss of revenue.

(c) *Second Repetitive Negligent Violation Within 3 Years of Violation Handled Under Paragraph (G)(2) or (G)(3).* The final penalty disposition shall be in an amount ranging from a minimum of 25 percent of the loss of revenue to a maximum of 50 percent of the loss of revenue.

(d) *Third and Each Subsequent Repetitive Negligent Violation Within 3 Years of Violation Handled Under Paragraph (G)(2) or (G)(3).* The final penalty disposition shall be in an amount ranging from a minimum of 50 percent of the loss of revenue to a maximum of 100 percent of the loss of revenue.

(e) *Fraudulent Violations.* The final penalty disposition shall be the same as in the case of fraudulent violations committed by persons who are not participants in the drawback compliance program (see paragraph (F)(2)(c)).

(5) *Final Penalty Disposition When There Has Been A Prior Disclosure.* The final penalty disposition shall be the same as in the case of persons who are not participants in the drawback compliance program (see paragraph (F)(3)).

PART 191—DRAWBACK

1. The authority citation for part 191 continues to read in part 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.

* * * * *

§§ 191.191–191.195 also issued under 19 U.S.C. 1593a.

2. In § 191.194, paragraphs (e) and (f) are revised to read as follows:

§ 191.194 Action on application to participate in compliance program.

* * * * *

(e) *Certification removal*—(1) *Grounds for removal.* The certification for participation in the drawback compliance program by a party may be removed when any of the following conditions are discovered:

(i) The certification privilege was obtained through fraud or mistake of fact;

(ii) The program participant is no longer in compliance with the Customs laws and regulations, including the requirements set forth in § 191.192;

(iii) The program participant repeatedly files false drawback claims or false or misleading documentation or other information relating to such claims; or

(iv) The program participant is convicted of any felony or has committed acts which would constitute a misdemeanor or felony involving theft, smuggling, or any theft-connected crime.

(2) *Removal procedure.* If Customs determines that the certification of a program participant should be removed, the applicable drawback office shall serve the program participant with written notice of the removal. Such notice shall inform the program participant of the grounds for the removal and shall advise the program participant of its right to file an appeal of the removal in accordance with paragraph (f) of this section.

(3) *Effect of removal.* The removal of certification shall be effective immediately in cases of willfulness on the part of the program participant or when required by public health, interest, or safety. In all other cases, the removal of certification shall be effective when the program participant has received notice under paragraph (e)(2) of this section and either no appeal has been filed within the time limit prescribed in paragraph (f)(2) of this section or all appeal procedures thereunder have been concluded by a decision that upholds the removal action. Removal of certification may subject the affected person to penalties.

(f) *Appeal of certification denial or removal*—(1) *Appeal of certification denial.* A party may challenge a denial of an application for certification as a participant in the drawback compliance program by filing a written appeal, within 30 days of issuance of the notice of denial, with the applicable drawback

office. A denial of an appeal may itself be appealed to Customs Headquarters, Office of Field Operations, Office of Trade Operations, within 30 days after issuance of the applicable drawback office's appeal decision. Customs Headquarters will review the appeal and will respond with a written decision within 30 days after receipt of the appeal unless circumstances require a delay in issuance of the decision. If the decision cannot be issued within the 30-day period, Customs Headquarters will advise the appellant of the reasons for the delay and of any further actions which will be carried out to complete the appeal review and of the anticipated date for issuance of the appeal decision.

(2) *Appeal of certification removal.* A party who has received a Customs notice of removal of certification for participation in the drawback compliance program may challenge the removal by filing a written appeal, within 30 days after issuance of the notice of removal, with the applicable drawback office. A denial of an appeal may itself be appealed to Customs Headquarters, Office of Field Operations, Office of Trade Operations, within 30 days after issuance of the applicable drawback office's appeal decision. Customs Headquarters shall consider the allegations upon which the removal was based and the responses made thereto by the appellant and shall render a written decision on the appeal within 30 days after receipt of the appeal.

Approved: August 3, 1998.

Robert S. Trotter,

Acting Commissioner of Customs.

Dennis M. O'Connell,

Acting Deputy Assistant Secretary of the Treasury.

[FR Doc. 98–25895 Filed 9–28–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 807

[Docket No. 98N–0520]

Medical Devices; Establishment Registration and Device Listing for Manufacturers and Distributors of Devices; Companion to Direct Final Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend certain regulations governing establishment registration and device listing by domestic distributors. This proposed rule is a companion document to the direct final rule published elsewhere in this issue of the **Federal Register**. These amendments are being made to implement revisions to the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Food and Drug Administration Modernization Act of 1997 (FDAMA). This companion proposed rule is being issued under FDAMA and the act as amended.

DATES: Comments must be received on or before December 14, 1998.

ADDRESSES: Submit written comments on the companion proposed rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Walter W. Morgenstern, Center for Devices and Radiological Health (HFZ–305), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20852.

SUPPLEMENTARY INFORMATION:

I. Background

This proposed rule is a companion to the direct final rule published in the final rules section of this issue of the **Federal Register**. The direct final rule and this companion proposed rule are substantively identical. FDA is publishing the direct final rule because the rule contains noncontroversial changes, and FDA anticipates that it will receive no significant adverse comment. A detailed discussion of this rule is set forth in the preamble of the direct final rule. If no significant adverse comment is received in response to the direct final rule, no further action will be taken related to this proposed rule. Instead, FDA will publish a confirmation document within 30 days after the comment period ends confirming that the direct final rule will go into effect on February 11, 1999. Additional information about FDA's direct final rulemaking procedures is set forth in a guidance published in the **Federal Register** of November 21, 1997 (62 FR 62466).

If FDA receives any significant adverse comment regarding the direct final rule, FDA will publish a document withdrawing the direct final rule within 30 days after the comment period ends and will proceed to respond to all of the comments under this companion proposed rule using usual notice-and-comment procedures. The comment period for this companion proposed rule runs concurrently with the direct final rule's comment period. Any comments received under this companion proposed rule will also be considered as comments regarding the direct final rule.

A significant adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. In determining whether a significant adverse comment is sufficient to terminate a direct final rulemaking, FDA will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process. Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered adverse under this procedure. For example, a comment recommending a rule change in addition to the rule will not be considered a significant adverse comment, unless the comment states why the rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to part of a rule and that part can be severed from the remainder of the rule, FDA may adopt as final those parts of the rule that are not the subject of a significant adverse comment.

This action is part of FDA's continuing effort to achieve the objectives of the President's ''Reinventing Government'' initiative, and is intended to reduce the burden of unnecessary regulations on medical devices without diminishing the protection of public health.

On November 21, 1997, the President signed FDAMA into law (Pub. L. 105–115). Section 213(b) of FDAMA made the following changes to section 510(g) of the act (21 U.S.C. 360(g)) regarding establishment registration and device listing by domestic distributors:

1. FDAMA amended section 510(g) of the act to add a new paragraph (g)(4) to provide that the registration and listing requirements of section 510 of the act do not apply to distributors who act as ''wholesale distributors,'' and who do not manufacture, repackage, process, or relabel a device.

2. FDAMA also added a definition of ''wholesale distributor'' to section 510(g) of the act. A ''wholesale distributor'' is defined as ''any person (other than the manufacturer or the initial importer) who distributes a device from the original place of manufacture to the person who makes the final delivery or sale of the device to the ultimate consumer or user.''