

administered by Customs unless such law specifies different procedures. Section 1526(f), however, specifies a different procedure for imposing civil fines for the importation of merchandise bearing a counterfeit mark. Therefore, the formula for civil fines set forth in section 1526(f) is controlling, and the domestic value appraisement rule of section 1606 and § 162.43(a) does not apply for that purpose.

Based on the foregoing, Customs believes that the term "domestic value" should be removed from § 133.27, leaving "manufacturer's suggested retail price" as the applicable measure of the penalty. The result would be that the formula for setting the maximum civil fine under the regulation would more closely follow the language of the statute. This would clarify for Customs personnel and the importing public the limit of a civil fine and would enhance uniformity in Customs assessment of fines when merchandise bearing a counterfeit mark is imported and seized. In addition, as the MSRP of a given article (in this case the genuine article that corresponds to imported merchandise bearing a counterfeit mark) is normally greater than its domestic value, because MSRP excludes retail sales and mark-downs, civil fines based on the MSRP will normally be greater. Thus, uniform application of the regulation will ensure that the Congressional intent in enacting section 1526(f), i.e., to enhance deterrence of trade in counterfeit goods, is uniformly served.

Customs notes that guidelines for the mitigation of penalties assessed under section 1526(f) and § 133.27 were published in T.D. 99-76 (33 Cust. Bull. No. 43, October 27, 1999). However, as the guidelines also use the term "domestic value" in the same manner as § 133.27, if the proposed rule is adopted as final, Customs will modify the guidelines to more closely adhere to the language of section 1526(f).

Executive Order 12866

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

Regulatory Flexibility Act

The proposed amendment, if adopted as final, will result in the language of the regulation more closely adhering to the language of the statute, thus clarifying the maximum amount Customs can assess for a civil fine when merchandise bearing a counterfeit mark is imported and seized. Pursuant to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601, *et seq.*), it is certified that the proposed amendment, if

adopted, will not have a significant economic impact on a substantial number of small entities. Accordingly, the proposed amendment is not subject to the regulatory analysis or other requirements of 5 U.S.C. 603 and 604.

Drafting Information

The principal author of this document was Bill Conrad, Office of Regulations and Rulings, U.S. Customs Service. However, personnel from other offices contributed in its development.

List of Subjects in 19 CFR Part 133

Counterfeit goods, Penalties, Seizures and forfeitures, Trademarks.

Proposed Amendment to the Regulations

For the reasons stated in the preamble, it is proposed to amend part 133 of the Customs Regulations (19 CFR part 133) as follows:

PART 133—TRADEMARKS, TRADE NAMES, AND COPYRIGHTS

1. The authority citation for part 133 continues to read, in part, as follows:

Authority: 17 U.S.C. 101, 601, 602, 603; 19 U.S.C. 66, 1624; 31 U.S.C. 9701.

* * * * *

2. Section 133.27 is revised to read as follows:

§ 133.27 Civil fines for those involved in the importation of merchandise bearing a counterfeit mark.

In addition to any other penalty or remedy authorized by law, Customs may impose a civil fine under 19 U.S.C. 1526(f) on any person who directs, assists financially or otherwise, or aids and abets the importation of merchandise for sale or public distribution that bears a counterfeit mark resulting in a seizure of the merchandise under 19 U.S.C. 1526(e) (see § 133.21 of this subpart), as follows:

(a) *First violation.* For the first seizure of merchandise under this section, the fine imposed will not be more than the value the merchandise would have had if it were genuine, according to the manufacturer's suggested retail price at the time of seizure.

(b) *Subsequent violations:* For the second and each subsequent seizure under this section, the fine imposed will not be more than twice the value the merchandise would have had if it were genuine, according to the

manufacturer's suggested retail price at the time of seizure.

Robert C. Bonner,
Commissioner of Customs.

Approved: June 3, 2002.

Timothy E. Skud,
Deputy Assistant Secretary of the Treasury.
[FR Doc. 02-14287 Filed 6-6-02; 8:45 am]

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DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Parts 141 and 151

RIN 1515-AD05

Conditional Release Period and Customs Bond Obligations for Food, Drugs, Devices, and Cosmetics

AGENCY: Customs Service, Department of the Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document proposes to amend the Customs Regulations to clarify the responsibilities of importers of food, drugs, devices, and cosmetics under Customs entry bond and to provide a reasonable period of time to allow the Food and Drug Administration to perform its enforcement functions with respect to these articles. The proposed amendments provide for a specific conditional release period for any food, drug, device, or cosmetic which has been released under bond and for which admissibility is to be determined under the provisions of the Food, Drug and Cosmetic Act. The proposed amendment also clarifies the amount of liquidated damages that may be assessed when there is a breach of the terms and conditions of the Customs bond. The document also proposes to amend the Customs Regulations to authorize any representative of the Food and Drug Administration (FDA) to obtain a sample of any food, drug, device, or cosmetic, the importation of which is governed by section 801 of the Food, Drug and Cosmetic Act, as amended (21 U.S.C. 381).

DATES: Comments must be received on or before August 6, 2002.

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: Jeremy Baskin, Office of Regulations and Rulings, Penalties Branch (202-927-2344).

SUPPLEMENTARY INFORMATION:

Background

Section 801 of the Food, Drug and Cosmetic Act, as amended (21 U.S.C. 381), and the regulations promulgated under that statute, provide the basic legal framework governing the importation of foodstuffs into the United States. Under 21 U.S.C. 381(a), the Secretary of the Treasury will deliver to the Secretary of Health and Human Services, upon request, samples of food, drugs, devices, and cosmetics which are being imported or offered for import. The Secretary of Health and Human Services is authorized under section 381(a) to refuse admission of, among other things, any article that appears from the examination or otherwise to be adulterated or misbranded or to have been manufactured, processed, or packed under insanitary conditions. In addition, the Secretary of the Treasury is required by section 381(a) to cause the destruction of any article refused admission unless the article is exported, under regulations prescribed by the Secretary of the Treasury, within 90 days of the date of notice of the refusal or within such additional time as may be permitted pursuant to those regulations.

Under 21 U.S.C. 381(b), pending decision as to the admission of an article being imported or offered for import, the Secretary of the Treasury may authorize delivery of that article to the owner or consignee upon the execution by him of a good and sufficient bond providing for the payment of liquidated damages in the event of default, as may be required pursuant to regulations of the Secretary of the Treasury. In addition, section 381(b) allows the owner or consignee in certain circumstances to take action to bring an imported article into compliance for admission purposes under such bonding requirements as the Secretary of the Treasury may prescribe by regulation.

Based upon the above statutory provisions, imported foods, drugs, devices, and cosmetics are conditionally released under bond while determinations as to admissibility are made; see § 12.3 of the Customs Regulations (19 CFR 12.3). Under current § 141.113(c) of the Customs Regulations (19 CFR 141.113(c)),

Customs may demand the return to Customs custody of most types of merchandise that fail to comply with the laws or regulations governing their admission into the United States (also referred to as the redelivery procedure).

The condition of the basic importation and entry bond contained in § 113.62(d) of the Customs Regulations (19 CFR 113.62(d)) sets forth the obligation of the importer of record to timely redeliver released merchandise to Customs on demand and provides that a demand for redelivery will be made no later than 30 days after the date of release of the merchandise or 30 days after the end of the conditional release period, whichever is later. Under current procedures, when imported merchandise is refused admission by the FDA, Customs issues a notice of redelivery in order to establish liquidated damages if the importer of record fails to export, destroy, or redeliver the refused merchandise in the time period prescribed in that notice of redelivery.

Customs has taken the position in C.S.D. 86-21 that the term "end of the conditional release period" in 19 CFR 113.62(d) has reference to a set time limitation that is either established by regulation (*see*, for example, 19 CFR 141.113(b) which prescribes a 180-day conditional release period for purposes of determining the correct country of origin of imported textiles and textile products) or is established by express notification to the importer of record. The end of the conditional release period does not refer to the liquidation of the entry covering the imported merchandise.

In light of the above authorities, Customs now proposes to amend the regulations to provide for a specific conditional release period for merchandise for which the FDA is authorized to determine admissibility. The proposed changes will clarify importers' responsibilities under the bond, provide a reasonable period of time to allow the FDA to perform its enforcement functions, and provide finality to the process.

Proposed Regulatory Changes

This document proposes to make the following specific changes to the Customs Regulations to address these points:

1. It is proposed to redesignate some paragraphs in § 141.113 due to the addition of a new paragraph (c), which will provide for a specific conditional release period of 180 days for any food, drug, device, or cosmetic. The FDA will have this time period to make its

determination of admissibility. Similar to the case of textiles and textile products mentioned above, the proposed amendment specifies a 180-day conditional release period but also provides for a shorter period if FDA makes a determination of inadmissibility before the expiration of that 180-day period. It is noted that as a consequence of this new text, under 19 CFR 113.62(d), a demand for redelivery could be made up to 210 days (that is, 180 days plus 30 days) after the date of release of the merchandise. The proposed regulation will also make clear that the failure to redeliver merchandise will result in the assessment of liquidated damages equal to three times the value of the merchandise or equal to the domestic value of merchandise in those instances where the port director has required a bond equal to the domestic value as permitted by current § 12.3.

2. It is proposed to amend § 151.10 of the Customs Regulations (19 CFR 151.10) to authorize a representative of the FDA to obtain samples of food, drugs, devices, and cosmetic products covered by the Food, Drug and Cosmetic Act.

Comments

Before adopting these proposed regulatory amendments as a final rule, consideration will be given to any written comments timely submitted to Customs, including comments on the clarity of this proposed 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 regular business days between the hours of 9:00 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, DC.

Regulatory Flexibility Act and Executive Order 12866

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. The proposed regulatory amendments reflect current statutory requirements, and they will not require any additional action on the part of the public but rather are intended to facilitate Customs enforcement efforts involving existing import requirements. Accordingly, the proposed amendments are not subject to

the regulatory analysis or other requirements of 5 U.S.C. 603 and 604. Furthermore, this document does not meet the criteria for a "significant regulatory action" as specified in E.O. 12866.

List of Subjects

19 CFR Part 141

Bonds, Customs duties and inspection, Entry procedures, Imports, Prohibited merchandise, Release of merchandise.

19 CFR Part 151

Customs duties and inspection, Examination, Sampling and testing, Imports, Laboratories, Penalties, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

For the reasons stated above, it is proposed to amend parts 141 and 151 of the Customs Regulations (19 CFR part 141 and 151) as set forth below.

PART 141—ENTRY OF MERCHANDISE

1. The authority citation for part 141 continues to read in part as follows:

Authority: 19 U.S.C. 66, 1448, 1484, 1624.

* * * * *

Section 141.113 also issued under 19 U.S.C. 1499, 1623.

2. Section 141.113 is amended as follows:

a. Redesignate current paragraphs (c) through (h) as paragraphs (d) through (i),

b. Add a new paragraph (c), and

c. Amend redesignated paragraph (d) by removing the words "(a) or (b)" and adding "(a), (b), or (c)" after the words "for any reason not enumerated in paragraph." New paragraph (c) reads as follows:

§ 141.113 Recall of merchandise released from Customs custody.

* * * * *

(c) Food, drugs, and cosmetics. For purposes of determining the admissibility of any food, drug, device, and cosmetic imported pursuant to section 801 of the Food, Drug and Cosmetic Act (21 U.S.C. 381), as amended, the release from Customs custody of any such product will be deemed conditional during the 180-day period following the date of release. If before the end of the 180-day period the Food and Drug Administration (FDA) finds that a food, drug, device, or cosmetic is not entitled to admission into the commerce of the United States, it will communicate that fact to the port director who will demand the redelivery

of the product to Customs custody. Customs will issue a notice of redelivery within 30 days from the date the product was refused admission by the FDA. The demand for redelivery may be made contemporaneously with the notice of refusal issued by the FDA. A failure to comply with a demand for return to Customs custody made under this paragraph will result in the assessment of liquidated damages equal to three times the value of the merchandise involved unless the port director has prescribed a bond equal to the domestic value of the merchandise pursuant to section 12.3(b) of this Chapter.

* * * * *

PART 151—EXAMINATION, SAMPLING, AND TESTING OF MERCHANDISE

1. The general authority citation for part 151 is revised, and a specific authority citation for § 151.10 is added, to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Notes 23 and 24, Harmonized Tariff Schedule of the United States (HTSUS)), 1624.

Section 151.10 also issued under 21 U.S.C. 381;

* * * * *

2. In § 151.10, add a sentence at the end of the text to read as follows:

§ 151.10 Sampling.

* * * For purposes of determining admissibility, representatives of the Food and Drug Administration may obtain samples of any food, drug, device, or cosmetic, the importation of which is governed by section 801 of the Food, Drug and Cosmetic Act, as amended (21 U.S.C. 381).

Robert C. Bonner, Commissioner of Customs.

Approved: June 3, 2002.

Timothy E. Skud, Deputy Assistant Secretary of the Treasury. [FR Doc. 02-14286 Filed 6-6-02; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[FRL-7222-2]

RIN 2060-AG91

National Emission Standards for Hazardous Air Pollutants for Source Categories: Generic Maximum Achievable Control Technology Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; amendments.

SUMMARY: We are proposing to amend the National Emission Standards for Hazardous Air Pollutants for Source Categories: Generic Maximum Achievable Control Technology Standards to revise the definition of the term "process vent" and to correct some editorial, cross-reference, and wording errors. In the Rules and Regulations section of this Federal Register, we are taking direct final action on the proposed amendments because we view these actions as noncontroversial, and we anticipate no adverse comments. We have explained our reasons for these actions in the preamble to the direct final rule. If we receive no significant adverse comments, we will take no further action on this proposed rule. If we receive significant adverse comments, we will withdraw only those provisions on which we received significant adverse comments. We will publish a timely withdrawal in the Federal Register indicating which provisions will become effective and which provisions are being withdrawn. If part or all of the direct final rule in the Rules and Regulations section of this Federal Register is withdrawn, all public comments pertaining to those provisions will be addressed in a subsequent final rule based on this proposed rule. We will not institute a second comment period on this action. If you are interested in commenting, you must do so at this time.

DATES: Comments. We must receive written comments by July 8, 2002, unless a hearing is requested by June 17, 2002. If a hearing is requested, we must receive written comments by July 22, 2002.

Public Hearing. If anyone contacts us requesting to speak at a public hearing by June 17, 2002, a public hearing will be held on June 21, 2002.

ADDRESSES: Comments. By U.S. Postal Service, submit written comments (in duplicate if possible) to: Air and Radiation Docket and Information