TABLE 1.—COMPLIANCE TIMES

For airplanes on which—	Inspect—	And repeat the HFEC and detailed inspections thereafter at—
(1) An HFEC or a detailed inspection specified in Boeing Service Bulletin 737–53A1225, dated October 19, 2000, has not been done as of the effective date of this AD.	Before the accumulation of 15,000 total flight cycles, or within 4,500 flight cycles after the effective date of this AD, whichever occurs later.	Intervals not to exceed 6,000 flight cycles.
(2) An HFEC or detailed inspection specified in Boeing Service Bulletin 737–53A1225, dated October 19, 2000, has been done before the effective date of this AD.	Within 6,000 flight cycles since the last HFEC inspection, within 1,200 flight cycles since the last detailed inspection, or within 4,500 flight cycles after the effective date of this AD, whichever occurs later.	Intervals not to exceed 6,000 flight cycles.

Corrective Actions

(g) If any crack is detected during any inspection required by paragraph (f) of this AD, before further flight, repair or replace the vertical beam web and associated parts with a new vertical beam web, in accordance with the Accomplishment Instructions of Boeing Service Bulletin 737–53A1225, Revision 1, dated April 14, 2005, except as provided by paragraph (h) of this AD.

(h) If any damage is beyond the scope of the service bulletin or structural repair manual, before further flight, repair the damaged vertical beam web in accordance with a method approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA; or using a method approved in accordance with paragraph (m) of this AD.

Terminating Preventative Modification

(i) Before the accumulation of 50,000 total flight cycles, or within 25,000 flight cycles after the effective date of this AD, whichever occurs later, replace the vertical beams at buttock lines (BL) 5.7 and 17.0 of the BS 178 bulkhead, in accordance with the Accomplishment Instructions of Boeing Service Bulletin 737–53A1225, Revision 1, dated April 14, 2005. Accomplishing the replacement ends the repetitive inspections required by paragraph (f) of this AD.

(j) Actions done before the effective date of this AD in accordance with Boeing BOECOM M–7200–01–00546, dated March 1, 2001, are acceptable for compliance with the requirements of paragraph (i) of this AD.

Prior to or Concurrent Requirements

(k) For Group 1 airplanes identified in Boeing Service Bulletin 737–53A1225, Revision 1, dated April 14, 2005: Before or concurrently with the requirements of paragraph (i) of this AD, do the preventative modifications of the center web, vertical chords, and side chord areas, including the side chord areas at water line 207, of the forward pressure bulkhead, specified in paragraph (c) of AD 2000–05–29, amendment 39–11639 (reference Boeing Alert Service Bulletin 737–53A1173, Revision 3, dated May 6, 1999).

(l) For Group 2 airplanes identified in Boeing Service Bulletin 737–53A1225, Revision 1, dated April 14, 2005: Before or concurrently with the requirements of paragraph (i) of this AD, but no later than the time specified in AD 2001–02–01, amendment 39–12085, do the preventative modifications of the vertical and side chord areas of the forward pressure bulkhead required by paragraph (c) of AD 2001–02–01 (reference Boeing Alert Service Bulletin 737–53A1208, dated May 6, 1999).

Alternative Methods of Compliance (AMOCs)

(m)(1) The Manager, Seattle ACO, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) Before using any AMOC approved in accordance with § 39.19 on any airplane to which the AMOC applies, notify the appropriate principal inspector in the FAA Flight Standards Certificate Holding District Office.

(3) An AMOC that provides an acceptable level of safety may be used for any replacement or repair required by this AD, if it is approved by an Authorized Representative for the Boeing Commercial Airplanes Delegation Option Authorization Organization who has been authorized by the Manager, Seattle ACO, to make those findings. For a replacement or repair method to be approved, the replacement or repair must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) Approved AMOCs to paragraph (c) of AD 2000–05–29 done before or concurrently with the requirements of paragraph (i) of this AD are approved as AMOCs for the corresponding provisions of paragraph (k) of this AD.

(5) Approved AMOCs to paragraph (c) of AD 2001–02–01 done before or concurrently with the requirements of paragraph (i) of this AD are approved as AMOCs for the corresponding provisions of paragraph (l) of this AD.

Material Incorporated by Reference

(n) You must use Boeing Service Bulletin 737–53A1225, Revision 1, dated April 14, 2005, to perform the actions that are required by this AD, unless the AD specifies otherwise. The Director of the Federal Register approved the incorporation by reference of this document in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207, for a copy of this service information. You may review copies at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., Room PL–401, Nassif Building, Washington, DC; on the Internet at *http://dms.dot.gov*; or at the National Archives and Records Administration (NARA). For information on the availability of this material at the NARA, call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

Issued in Renton, Washington, on January 19, 2007.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E7–1396 Filed 1–30–07; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Bureau of Customs and Border Protection

DEPARTMENT OF THE TREASURY

19 CFR Parts 113, 141, and 151

[CBP Dec. 07–02]

RIN 1505–AB57

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

AGENCIES: Customs and Border Protection, Department of Homeland Security; Department of the Treasury.

ACTION: Final rule.

SUMMARY: This document amends the Customs and Border Protection (CBP) regulations to clarify the responsibilities of importers of food, drugs, devices, and cosmetics under the basic CBP importation bond and to provide a reasonable period of time to allow the Food and Drug Administration (FDA) to perform its enforcement functions with respect to these covered articles. The amendments include a provision for a specific conditional release period of 30 days 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 Federal Food, Drug, and Cosmetic Act (the Act). The amendments also clarify the amount of liquidated damages that may be assessed when there is a breach of the terms and conditions of the bond and authorize any representative of FDA to obtain a sample of any imported article subject to section 801 of the Act, as amended.

DATES: *Effective Date:* The amendments set forth in this document are effective on May 1, 2007.

FOR FURTHER INFORMATION CONTACT: Wende Schuster, Office of International Trade, (202–572–8761).

SUPPLEMENTARY INFORMATION:

Background

Federal Food, Drug, and Cosmetic Act

Section 801 of the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 381 referred to herein as section 381), and the regulations promulgated under that statute, provide the basic legal framework governing the importation of food, drugs, devices, and cosmetics into the United States. Under 21 U.S.C. 381(a), the Secretary of the Treasury shall 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 (by FDA) 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 regulation. 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.

Authority Delegation

On November 25, 2002, the President signed into law the Homeland Security Act of 2002, Public Law 107–296, 116 Stat. 2135 (referred to in this document as ''the HS Act''), which involved, among other things, the creation of a new cabinet-level department, the Department of Homeland Security (DHS), and the transfer or reorganization of a number of executive branch agencies and offices within existing cabinet-level departments. This legislation and subsequent reorganization plans affected the organization and operation of the Customs Service.

Section 402 of the HS Act provides that the Secretary of Homeland Security shall be responsible for administering the customs laws of the United States. With regard to the Customs Service, section 403(1) of the HS Act transferred the functions, personnel, assets, and liabilities of the Customs Service, including the functions of the Secretary of the Treasury relating to the Customs Service, to the Secretary of Homeland Security. However, notwithstanding the transfer of the Customs Service to DHS, section 412 of the HS Act provides that the legal authority vested in the Secretary of the Treasury over customs revenue functions is to be retained by the Secretary of the Treasury. Section 412 also authorizes the Secretary of the Treasury to delegate any of the retained legal authorities over the customs revenue functions to the Secretary of Homeland Security.

By Treasury Order 100–16, dated May 15, 2003, the Secretary of the Treasury, by virtue of authority vested in him/her by 31 U.S.C. 321(b) and section 412 of the Homeland Security Act of 2002, delegated to the Secretary of Homeland Security authority for customs revenue functions with certain exceptions, including that contained in paragraph (1)(a)(i) of the Order by which the Secretary of the Treasury retains the sole authority to approve regulations concerning import quotas or trade bans, user fees, marking, labeling, copyright and trademark enforcement, and the completion of entry or substance of entry summary including duty assessment and collection, classification, valuation, application of the U.S. Harmonized Tariff Schedules, eligibility or requirements for preferential trade programs, and establishment of related recordkeeping requirements. As this final rule concerns activities involving both the completion of entry and the substance of the entry summary focusing on bond obligations and consequences that might arise as a result of post-entry and post-summary determinations of admissibility of merchandise, its subject matter is excepted from the delegation of authority to the Secretary of Homeland Security. Thus, the responsibility for this regulation rests with the Secretary of the Treasury.

Applicable Regulations

Based upon the above Federal Food, Drug, and Cosmetic Act statutory provisions, imported foods, drugs, devices, and cosmetics are conditionally released under bond while determinations as to admissibility are made; *see* 19 CFR 12.3. Under current 19 CFR 141.113(c), CBP may demand the return to CBP 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 19 CFR 113.62(d) sets forth the obligation of the importer of record to timely redeliver released merchandise to CBP 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 Food and Drug Administration (FDA), CBP issues a notice of redelivery in order to establish a claim for 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.

CBP 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 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.

Proposed Regulatory Changes

On June 7, 2002, a Notice of Proposed Rulemaking was published in the **Federal Register** (67 FR 39322; the NPRM) that proposed to amend the regulations to provide for a specific conditional release period for

merchandise for which the FDA is authorized to determine admissibility. The changes proposed were intended to clarify importers' responsibilities under the bond, provide a defined period of time to allow the FDA to perform its enforcement functions, and provide finality to the process.

The NPRM proposed to make the following specific changes to what were then referred to as the Customs regulations (now the CBP regulations):

1. To redesignate some paragraphs in 19 CFR 141.113 due to the addition of a new paragraph (c), which provided for a specific conditional release period of 180 days for any food, drug, device, or cosmetic. The FDA would have this time period to make its determination of admissibility. Similar to the case of textiles and textile products mentioned above, the proposed amendment specified a 180-day conditional release period but also provided for a shorter period if FDA made a determination of inadmissibility before the expiration of that 180-day period. It is noted that under the proposed regulatory text, a demand for redelivery under 19 CFR 113.62(d) could be made up to 210 days (that is, 180 days plus 30 days) after the date of release of the merchandise. (The standard CBP bond condition states that redelivery may be demanded within 30 days after release or 30 days after the end of any applicable conditional release period, whichever is later.) The proposed regulation also made clear that the failure to redeliver merchandise would result in the assessment of liquidated damages equal to three times the value of the merchandise or equal to the domestic value of the merchandise in those instances where the port director has required a bond equal to the domestic value as permitted by current 19 CFR 12.3.

2. To amend 19 CFR 151.11 to authorize a representative of the FDA to obtain samples of food, drugs, devices, and cosmetic products covered by the Federal Food, Drug, and Cosmetic Act.

Comments

One hundred and forty (140) comments were received from importers, brokers, sureties, freight forwarders, express consignment operators, and trade associations. All commenters were opposed to the length of time of the proposed conditional release period. An analysis of those comments follows.

Comment

The vast majority of commenters stated that, as importers of food and health and beauty aid products, having a conditional release period of 180 days would effectively put them out of business. The costs involved in warehousing the goods would make their businesses unmanageable. Additionally, the long waiting period could cause products to fall out of specification, lose effectiveness, or become obsolete or unusable. These comments assume that any FDA-regulated merchandise must be held intact for 180 days after entry. Other commenters who stated that the 180-day period is too long recognize that the intent of the regulation was not to require that all this merchandise be held during the pendency of the conditional release period, but rather that it only apply to merchandise for which an admissibility decision by FDA is not made. Many of these commenters specifically recommended that the conditional release period end upon issuance of a notice from FDA providing that the goods may proceed (a may proceed notice) or issuance of a notice of refusal if those acts occur before the end of the 180-day conditional release period. Various other commenters noted that under FDA's own Regulatory Procedures Manual, articles which have been released by FDA are no longer considered to be in import status by that agency.

Response

After review of all the comments, CBP concurs that the 180-day conditional release period is too long. Thus, the regulatory text of this final rule is amended to provide that the conditional release period ends upon the soonest occurring of the following events: issuance by the FDA that the merchandise may proceed, issuance of a notice of refusal of admission, or expiration of the 30-day period after release of the goods.

It was not the intention of the proposed regulation to require that all goods regulated by the FDA be warehoused for 6 months while the conditional release period runs its course. When FDA issues a notice that the merchandise may proceed (which is the case on the vast majority of entries that come under FDA scrutiny), that act will serve to end the conditional release period. Accordingly, we concur with the commenter who recommended amendment of the proposed rule to indicate that the conditional release period ends upon issuance of the notice by FDA that the merchandise may proceed. In addition, the issuance of a notice of refusal of admission would end the conditional release period.

There may be some situations where FDA will need additional time to determine admissibility. Accordingly, the final rule also includes regulatory language that would permit FDA to extend the general 30-day conditional release period through express notification to the importer identifying the necessary testing requiring this extension.

Comment

Many commenters opposed the 180-day conditional release period for the reason that it extends the current conditional release period of 30 days.

Response

Under the conditions of the basic importation bond, in order to establish a valid claim for liquidated damages for failure to redeliver merchandise into CBP custody, CBP must issue a notice of redelivery within 30 days of CBP release of merchandise or within 30 days after the end of the conditional release period, whichever is later. As stated in the notice of proposed rulemaking, there currently exists no conditional release period created by regulation for merchandise the admissibility of which is determined by the FDA. Therefore, neither the proposed rulemaking nor this final rule extends the conditional release period from 30 to 180 days because no express conditional release period for FDA contexts has ever been created by regulation. The commenters were apparently confusing the conditional release period with the 30-day period, after the conditional release period, during which CBP may still demand redelivery.

Comment

One commenter suggested that the proposed sampling procedures would result in the compromising of its packaging between manufacturing sites and customers' facilities. The commenter proposed a process whereby it and other manufacturers could provide dedicated samples of present and proposed imported products, and CBP could maintain a data bank of importers and known imported products covered by these regulations.

Response

The commenter's suggestion is outside the scope of the regulation because it proposes an examination procedure that is not done on a shipment-by-shipment basis. Under the provisions of 21 U.S.C. 381, CBP delivers to the Secretary of Health and Human Services such samples of food, drugs, devices, and cosmetics that are being imported or offered for import into the United States. Through these regulations, this sampling authority is

delegated to the FDA in recognition of the practicalities of merchandise inspection. This will clarify that FDA inspectors may, under section 381(a), pull samples of imports of food, drugs, devices, and cosmetics.

Comment

One commenter asked whether CBP contemplates changing line release (otherwise known as Border Release Advanced Screening and Selectivity (BRASS)) procedures to accommodate the exchange of information necessary for providing notices of sampling.

Response

Contemplated changes to line release (otherwise known as BRASS release) systems are operational in nature and are, thus, outside the scope of this rulemaking.

Comment

One commenter suggested that the rule must be rescinded in order to comply with Executive Order (E.O.) 12866. The commenter stated that given the huge volume of imports involved, the storage costs alone would almost certainly exceed the $100 million threshold or would, at the very least, adversely affect in a material way the economy, a sector of the economy, productivity, competition, or jobs.

Response

The commenter did not provide detail or justification for these comments, but CBP does not believe that storage costs of this magnitude would be incurred as a result of the rule now being promulgated. As noted above, CBP does believe that the 180-day conditional release period originally proposed is too long and realizes that this time period could negatively affect importers. To that end, CBP has modified the conditional release period from 180 days to 30 days in the final rule to reduce potential negative impacts to imports and corresponding storage costs.

Comment

Various commenters state that CBP has failed to comply with the Regulatory Flexibility Act, disagreeing with the statement in the proposed rulemaking that the proposed amendments, if adopted, will not have a significant impact on a substantial number of small entities. The commenters claim that, contrary to the assertion in the notice of proposed rulemaking, assessment of liquidated damages of three times the value of imported merchandise could have a devastating impact upon the many thousands of small companies engaged in the importation of FDA-regulated products. It is also stated that the proposed rulemaking represents a radical departure from current CBP policy with regard to redelivery of FDA-regulated products.

Response

CBP does not agree because the rule is not a radical departure from current CBP policy. Additionally, in response to the comments to the proposed rule, the final rule reduces the conditional release period time from 180 days to 30 days, and potential costs that could be incurred should now be substantially less. The rule should not affect small entities that are compliant with redelivery requirements, and the rule does not impose further entry requirements or additional paperwork burden.

Comment

Various commenters suggested that CBP rescind or place a stay on consideration of the proposed rulemaking until the implications of recently passed legislation governing port security can be considered in relation to FDA's inspection protocol and CBP's release procedures. The commenters indicated that the new law requires that importers provide CBP and FDA with advance notice of their intent to import food products—a procedure that should enhance FDA's ability to promptly identify shipments that pose a safety concern. Those commenters also stated that the proposed rule should be rescinded in order to allow CBP and FDA to examine and discuss standardization of FDA notifications to importers and to take into account the commercial needs of the importing community.

Response

CBP disagrees. We are unaware of legislation governing port security that impinges upon or supplants FDA's authority to refuse merchandise pursuant to the provisions of 21 U.S.C. 381(a). That provision allows for the release of merchandise under bond while the determination as to admissibility is made. This rulemaking simply provides for the creation of a conditional release period for FDA contexts that is more clearly defined than the practice that currently exists. Furthermore, the Bioterrorism Act creates a new section 21 U.S.C. 381(m), which specifically indicates that FDA-regulated food and food products for which prior notice of arrival is not received shall not be released under a bond authorized by section 381(b). As set out in implementing regulations issued by FDA and CBP (see 68 FR 58974), decisions regarding compliance with new prior notice requirements are different from, and may precede, determinations of admissibility under other sections of the Federal Food, Drug, and Cosmetic Act or other laws. (*See* 21 CFR 1.283(g).) While CBP believes that the Bioterrorism Act will affect the importation of FDA-regulated products, it does not serve to overrule regulations concerning longstanding FDA and CBP authorities. Effect must be given to all of the substantive provisions of 21 U.S.C. 381, not part of them. Further, since the FDA-regulated food or food products for which prior notice of arrival is not received will not be released under a bond authorized by section 381(b), any issues arising concerning a conditional release period for merchandise released under bond are moot.

Comment

One commenter suggested that the time period to comment on the proposed rule be extended because of the complex underlying issues involved.

Response

CBP disagrees that the comment period needed to be extended. CBP received 140 comments to the proposed rule, and a wide variety of issues were presented in these comments. The primary concern, which was raised by all commenters to the proposed rule, was the length of the conditional release period. In response to this concern CBP has reduced the conditional release period from 180 to 30 days.

Comment

Many commenters conceded that it may be appropriate to clearly define a conditional release period, but they also suggested that 30 days would be a reasonable conditional release period for these products. Those same commenters also stated that CBP must further clarify and limit the scope of the proposed rule. Clarification is needed that clearly exempts from the conditional release period shipments that have been issued a may proceed notice. The commenters also suggested that FDA should notify importers when an entry is deemed conditional. As proposed, the commenters claimed that the rule represents a radical departure from current practices when the release of imported product is only rendered conditional through FDA's timely notification of its intent to examine or sample the product.

Response

CBP agrees that the rule should make clear that a conditional release period ends when FDA provides a may proceed notice. The final rule has been amended accordingly. CBP also agrees that a conditional release period shorter than 180 days is appropriate and has amended the rule to provide for a conditional release period of 30 days after the release of the merchandise unless FDA issues a may proceed notice or a notice of refusal which would immediately end the conditional period as provided for in the final rule. However, shipments that have been issued a may proceed notice are still subject to demands for redelivery for 30 days from the issuance of the may proceed notice. The regulation confirms that all FDA-regulated products under the Federal Food, Drug, and Cosmetic Act are conditionally released pending FDA's determination of admissibility. In the vast majority of cases the conditional release period will end when the may proceed notice is provided before the end of the time provided in the regulation.

Comment

Various commenters contended that CBP seeks to modify its regulations in order to reverse the result of the court decision in *United States* v. *So's USA Company, Inc.,* 23 CIT 605 (1999). These commenters stated that the *So's* court indicated that an importer must have affirmative notice that goods are released conditionally in order to extend the redelivery period beyond the 30 days from the date of release. Another stated that under the proposed regulation, FDA would no longer be required to advise an importer why its product is on hold, or even that it is on hold, within the first 30 days of entry.

Response

CBP disagrees. The final rule is entirely consistent with the So's opinion and it does not conflict with that opinion in any respect. Further, this regulation does not affect any notice that FDA provides to an importer under its authorities.

Comment

One commenter stated that the proposal is arbitrary because the Government has not explained the need for a 180-day period to render a decision on admissibility. The statement in the proposed rule that the 180-day period is a reasonable period of time to allow the FDA to perform its enforcement functions is not supported by any explanation.

Response

Again, CBP agrees that the 180-day period is too long a time period to have this merchandise conditionally released by regulation. Accordingly, the conditional release period has been reduced to 30 days in the final regulation. The 30-day release period can be shortened by the earlier issuance of a may proceed notice or a notice of refusal of admission. It also can be extended by an express notification from FDA to the importer.

Comment

One commenter suggested that FDA import inspectors issue a notice of review with regard to any shipment for which a may proceed notice is not provided. The commenter stated that the conditional release period could be established from the issuance date of the notice of review. That same commenter stated that for perishable products, the conditional release period should not exceed 5 days. For non-perishable products, the conditional release period should not exceed 30 days.

Response

Issuance of a new FDA form of notice that a shipment is under review is beyond the scope of this regulation. CBP disagrees that a conditional release period should be for as little as 5 days. The taking of samples and testing of merchandise could exceed that 5-day time period.

Comment

Some commenters stated that the 180-day conditional release period is not consistent with the Customs-Trade Partnership Against Terrorism (C-TPAT) in that homeland security efforts are focused on increased review of imports at the time of admission. The proposed 180-day period would provide no potential homeland security benefits since the materials would already be conditionally released to importers.

Response

CBP acknowledges that the proposed 180-day conditional release period is too long and has revised the regulation accordingly. Review of cargo for terrorism concerns preferably is performed earlier than the time of admission of merchandise. In fact, review for terrorism concerns is performed in the information transmission or presentation process, which is in advance of arrival. For example, the FDA's prior notice regulations (21 CFR 1.276 *et seq.*) require notice of food being imported or offered for import into the United States in advance of the foods' arrival, and CBP's advance electronic cargo information regulations (set forth in 68 FR 68140) require information concerning cargo before the cargo is brought into the United States by any mode of transportation, so that CBP can pre-screen all cargo based on advance data transmission. CBP's enforcement of these requirements is consistent with C-TPAT. The conditional release period is meant to address the longstanding application of the provisions of the Federal Food, Drug, and Cosmetic Act, which allow for the release of merchandise under good and sufficient bond pending an admissibility determination and therefore is in addition to the prior notice and advance cargo information requirements that implement border security measures.

Comment

Many commenters stated that a 180 day conditional release period is contrary to public policy in that merchandise which causes a public health or safety issue should be identified and refused by FDA as quickly as possible. A 180-day period raises an unreasonable risk.

Response

CBP has revised the regulation to provide for a 30-day conditional release period in order to address this concern.

Comment

Many commenters indicated that if the redelivery period was shorter than the 180-days prescribed, companies would hold merchandise pending such a period and there would be more chance for a successful recall for safety concerns, since there is less chance that the goods would have been used or consumed.

Response

CBP agrees and has revised the final rule to provide for a 30-day conditional release period in order to address this concern.

Comment

One commenter suggested that CBP should strive to allow unconditional release of FDA-regulated merchandise with the filing of the CF–3461 (CBP entry document) as long as the entry summary and carrier manifest data are consistent with information contained within the FDA approved product listings.

Response

CBP disagrees because this would have CBP making decisions as to admissibility under the Federal Food, Drug, and Cosmetic Act when this

decision-making authority clearly resides with the Secretary of Health and Human Services.

Comment

Many commenters stated that the proposed amendment to 19 CFR 151.10 of the CBP regulations regarding the collection of samples is not necessary. The commenters noted that the provisions of section 702(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 372) already allow for the taking of samples by representatives of FDA.

Response

Under the provisions of 21 U.S.C. 381(a), CBP delivers samples of food, drugs, devices, and cosmetics that are being imported or offered for import into the United States, to the Secretary of Health and Human Services upon his request. The proposed amendment simply clarifies that such delivery authority is delegated to representatives of FDA and is not intended to intrude on any other authority that the Secretary of Health and Human Services may already have.

Comment

A group of commenters suggested the adoption of regulatory language that would preclude the issuance of fines or penalties against an importer who distributes articles after having received an FDA may proceed notice.

Response

CBP disagrees with this proposed language. CBP cannot by regulatory amendment exempt an importer from incurring fines or penalties that may otherwise be imposed for violation of a statute.

Comment

Various commenters stated that imposition of a 180-day conditional release period is violative of U.S. international obligations under the GATT 1994, and one commenter indicated that the proposed rule is violative of the Agreement on the Application of Sanitary and Phytosanitary Measures. While conceding that some additional controls at the border are acceptable, these commenters asserted that extending CBP control over imports for a seven-month period after importation would not stand scrutiny. Additionally, it was noted that sanitary and phytosanitary procedures must be undertaken and *completed without undue delay* (commenter's emphasis) and in no less favorable a manner for imported products than for like domestic products. Imposition of a conditional release period of 180 days is claimed to be violative of this ''undue delay'' proscription.

Response

Again, CBP has reduced the conditional release period from 180 to 30 days in the final rule.

Comment

Some commenters indicated that continuation of a conditional release period after FDA admits goods into commerce is inconsistent with the provisions of the Federal Food, Drug, and Cosmetic Act. The commenters stated that conditional delivery of the merchandise to the owner is made pending a decision as to admission generally, and not solely a decision to deny admission. It is argued that conditional release also ends upon admission of the article and, as such, CBP's proposal to extend the conditional release period to 180 days without concern as to whether the merchandise has been admitted defeats the statutory intent of the Act. In contrast, another commenter stated that once a positive determination as to admissibility is made, the importer should not have to be subjected to the possibility of a redelivery demand for sampling or testing of the product. The latter commenter further contended that even after receiving a may proceed notice, an importer is left in the dark as to the status of goods that are apparently admitted into the commerce.

Response

CBP agrees that issuance of a notice from FDA that the merchandise may proceed would usually make it unnecessary to issue a redelivery notice in order to establish liability under the bond. For purposes of clarity, CBP is amending the language in the final rule to indicate that one of three acts occurring first in time—issuance of a notice of refusal, issuance of a may proceed notice or passage of 30 days from the date of conditional release—will end the conditional release period. However, it should be understood that issuance of a may proceed notice does not mean that CBP is precluded from issuing a subsequent demand to redeliver within 30 days from the end of that conditional release period.

Comment

Two commenters suggested that sureties be given the earliest possible notice (preferably in electronic form) that goods they have secured are subject to detention, refusal, and/or redelivery in order that immediate action can be taken with regard to pending and future importations. Also, mitigation guidelines should be adopted that provide extraordinary mitigation to sureties for efforts to locate, redeliver, and/or rehabilitate goods which are subject to liquidated damages for failure to redeliver into CBP custody.

Response

Mitigation guidelines for claims for liquidated damages are outside the scope of this rulemaking. Issuance of notices of detention and refusal are governed by FDA statute and regulation and any changes to issuance of those documents are also outside the scope of this regulation. Notices of redelivery may include private or confidential business information that would not be releasable to a surety unless a demand for payment was made against its bond.

Comment

One commenter proposed that the regulation require that all demands for redelivery be made contemporaneously with the notice of refusal issued by FDA. The commenter contended that this change would promote cooperation between FDA and CBP and encourage compliance through the more efficient issuance of required notices.

Response

CBP does not agree because, for operational reasons, it may not always be possible for notices to be issued contemporaneously.

Conclusion

In accordance with the foregoing analysis of the comments and further consideration of the matter, CBP has determined that the amendments of the proposed rule should be adopted as final with the sole major change being a reduction in the conditional release period from 180 days to 30 days, as set forth in the regulatory text further below. In addition, cross-references to the section of the regulations involving conditional release periods are being added to the relevant portion of the section on basic importer and entry bond conditions in 19 CFR 113.62.

Executive Order 12866 and the Regulatory Flexibility Act

This rule is not considered to be a significant regulatory action under Executive Order 12866. Accordingly, a regulatory assessment is not required.

It is certified, pursuant to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), that the regulatory amendments set forth in this final rule will not have a significant economic impact on a substantial

number of small entities. The rule should not affect small entities that are compliant with redelivery requirements, and the rule does not impose further entry requirements or additional paperwork burdens.

A review of data for FY2004 indicates actual CBP liquidated damage collections for FDA jurisdiction goods are comparatively rare and of modest amounts. The total amount of liquidated damages collected in FY2004 for these goods was approximately $4 million. The total revenue (including those liquidated damages) collected for all imports was $27 billion. This amount reflects 6,000 liquidated damage cases, compared to 28.1 million entries of all goods worth $1.41 trillion. Pertinent cases and liquidated damage amounts are a tiny fraction (less than 1 percent) of overall revenue collected and import value. The value of liquidated damages collected changes minimally from year to year based on the number of importers, the number of bonds, and the number of violations. CBP does not expect this amount to change as a result of this rule.

Additionally, the conditional release period should help importers, regardless of size, by clarifying that CBP must issue a redelivery notice within 30 days if it wishes to collect liquidated damages. As noted previously, there is currently no set date to issue a redelivery notice. The rule will compel CBP to act more quickly to provide notice to importers that violate the conditions of their bond. If CBP cannot act within the 30 days, it then foregoes collecting any liquidated damages.

List of Subjects

19 CFR Part 113

Customs bond conditions.

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.

Amendments to the Regulations

■ For the reasons stated above, parts 113, 141, and 151 of the CBP regulations (19 CFR Parts 141 and 151) are amended as set forth below.

PART 113—CUSTOMS BOND CONDITIONS

■ 1. The authority citation for part 113 continues to read in part as follows:

Authority: 19 U.S.C. 66, 1623, 1624.

* * * * *

§ 113.62 [Amended]

■ 2. Section 113.62(d) is amended by adding a sentence at the end to read as follows: ''(See §§ 141.113(b), 12.73(b)(2), and 12.80 of this chapter.)''

PART 141—ENTRY OF MERCHANDISE

■ 3. 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.

■ 4. Section 141.113 is amended as follows:
■ a. The heading of the section is revised to read as set forth below;
■ b. Paragraph (a) is amended by, after the heading, designating the introductory text of paragraph (a) as paragraph (a)(1), redesignating current paragraphs (1) through (5) as paragraphs (a)(1)(i) through (v), and designating the remaining text, after redesignated paragraph (a)(1)(v), as paragraph (a)(2);
■ c. In redesignated paragraph (a)(2), first sentence, the words ''Customs custody'' are removed and replaced with the words ''CBP custody'';
■ d. In paragraph (b), the two references to ''Customs'' are replaced with reference to ''CBP'' and the three references to ''Customs custody'' are replaced with reference to ''CBP custody'';
■ e. Current paragraphs (c) through (h) are redesignated as paragraphs (d) through (i);
■ f. New paragraph (c) is added;
■ g. In redesignated paragraph (d), the words ''in paragraph (a) or (b) of this section'' are removed and replaced with the words ''in paragraph (a), (b), or (c) of this section'', and the words ''Customs custody'' are removed and replaced with the words ''CBP custody'';
■ h. In redesignated paragraphs (e) and (f), the words ''Customs custody'' are removed and replaced with the words ''CBP custody'';
■ i. In redesignated paragraph (g), first sentence, the words ''Customs custody'' are removed and replaced with the words ''CBP custody''; and
■ j. In redesignated paragraph (h) and in the first sentence of redesignated paragraph (i), the words ''Customs custody'' are removed and replaced with the words ''CBP custody''.

The revisions read as follows:

§ 141.113 Recall of merchandise released from Customs and Border Protection custody.

* * * * *

(c) *Food, drugs, devices, and cosmetics*—(1) *Conditional release period.* For purposes of determining the admissibility of any food, drug, device, or cosmetic imported pursuant to section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)), as amended, the release from CBP custody of any such product will be deemed conditional. Unless extended in accordance with paragraph (c)(2) of this section, the conditional release period will terminate upon the earliest occurring of the following events:

(i) The date that FDA issues a notice of refusal of admission;

(ii) The date that FDA issues a notice that the merchandise may proceed; or

(iii) Upon the end of the 30-day period following the date of release.

(2) *Extension of conditional release period.* The conditional release period provided under this paragraph (c) may be extended. The FDA must issue a written or electronic notice of sampling, detention, or other FDA action to the bond principal (i.e., importer of record) within 30 days of the release of the merchandise in order for the extension of the conditional release period to be valid.

(3) *Issuance of a redelivery notice.* If FDA refuses admission of a food, drug, device or cosmetic into the United States, or if any notice of sampling or other request is not complied with, FDA will communicate that fact to the CBP port director who will demand the redelivery of the product to CBP custody. CBP will issue a notice of redelivery within 30 days from the date the product was refused admission by the FDA or from the date FDA determined the noncompliance with a notice of sampling or other request. The demand for redelivery may be made contemporaneously with the notice of refusal issued by the FDA. Notwithstanding the provisions of paragraph (i) of this section, a failure to comply with a demand for redelivery made under this paragraph (c) 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 § 12.3(b) of this Chapter.

* * * * *

PART 151—EXAMINATION, SAMPLING, AND TESTING OF MERCHANDISE

■ 5. The general authority citation for part 151 continues to read, and a specific authority citation for § 151.11 is added to read, as follows:

Authority: 19 U.S.C. 66, 1202 (General Notes 3(i) and 3(j), Harmonized Tariff Schedule of the United States (HTSUS)), 1624.

Section 151.11 also issued under 21 U.S.C. 381;

* * * * *

■ 6. Section 151.11 is amended as follows:

■ a. In the first sentence, the words ''Customs custody'' are removed and replaced with the words ''CBP custody'';

■ b. In the second sentence, the words ''Customs custody'' are replaced with the words ''CBP custody''; and

■ c. After the second sentence, a third sentence is added, to read as follows:

§ 151.11 Request for samples or additional examination packages after release of merchandise.

* * * 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 Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 381).

Deborah J. Spero,

Acting Commissioner, Customs and Border Protection.

Approved: January 25, 2007.

Timothy E. Skud,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 07–408 Filed 1–30–07; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Saint Lawrence Seaway Development Corporation

33 CFR Part 402

[Docket No. SLSDC 2006–26584]

RIN 2135–AA25

Tariff of Tolls

AGENCY: Saint Lawrence Seaway Development Corporation, DOT.

ACTION: Final rule.

SUMMARY: The Saint Lawrence Seaway Development Corporation (SLSDC) and the St. Lawrence Seaway Management Corporation (SLSMC) of Canada, under international agreement, jointly publish and presently administer the St. Lawrence Seaway Tariff of Tolls in their respective jurisdictions. The Tariff sets forth the level of tolls assessed on all commodities and vessels transiting the facilities operated by the SLSDC and the SLSMC. The SLSDC is revising its regulations to reflect the fees and charges levied by the SLSMC in Canada starting in the 2007 navigation season, which are effective only in Canada. An amendment to increase the minimum charge per lock for those vessels that are not pleasure craft or subject in Canada to tolls under items 1 and 2 of the Tariff for full or partial transit of the Seaway will apply in the U.S. Also, the SLSDC is changing the toll charged per pleasure craft using the U.S. locks from $25 U.S. or $30 Canadian to $30 U.S. or $30 Canadian. Several minor editorial corrections are being made in § 402.3, ''Interpretation.'' and § 402.6, ''Description and weight of cargo.'' (See **SUPPLEMENTARY INFORMATION**.)

DATES: This rule is effective March 2, 2007.

FOR FURTHER INFORMATION CONTACT: Craig H. Middlebrook, Acting Chief Counsel, Saint Lawrence Seaway Development Corporation, 400 Seventh Street, SW., Washington, DC 20590, (202) 366–0091.

SUPPLEMENTARY INFORMATION: The Saint Lawrence Seaway Development Corporation (SLSDC) and the St. Lawrence Seaway Management Corporation (SLSMC) of Canada, under international agreement, jointly publish and presently administer the St. Lawrence Seaway Tariff of Tolls (Schedule of Fees and Charges in Canada) in their respective jurisdictions.

The Tariff sets forth the level of tolls assessed on all commodities and vessels transiting the facilities operated by the SLSDC and the SLSMC. The SLSDC is revising 33 CFR 402.8, ''Schedule of tolls'', to reflect the fees and charges levied by the SLSMC in Canada beginning in the 2007 navigation season. With one exception, the changes affect the tolls for commercial vessels and are applicable only in Canada. The collection of tolls by the SLSDC on commercial vessels transiting the U.S. locks is waived by law (33 U.S.C. 988a(a)). Accordingly, no notice or comment was necessary on these amendments.

The SLSDC is amending 33 CFR 402.8, ''Schedule of tolls'', to increase the minimum charge per vessel per lock for full or partial transit of the Seaway from $20.40 to $25.00. This charge is for vessels that are not pleasure craft or subject in Canada to the tolls under items 1 and 2 of the Tariff. This increase is due to higher operating costs at the locks.

The SLSDC is modifying its practice regarding the collection of pleasure craft tolls by allowing pleasure craft operators to pay the toll for transiting the U.S. locks, Eisenhower and Snell, in either $30 U.S. or $30 Canadian. Currently the toll is payable in $25 U.S. or $30 Canadian; however, this has resulted in confusion to pleasure craft operators when transiting both Canadian and U.S. locks. With almost eighty (80) percent of the tolls for pleasure crafts being paid in Canadian dollars and little disparity between the U.S. and Canadian exchange rates, the SLSDC is streamlining the pleasure craft toll collection process by allowing for payment in either $30 U.S. or $30 Canadian. Additionally, the SLSDC is making several minor editorial changes to 33 CFR402.3 and 33 CFR 402.5. Interested parties have been afforded an opportunity to comment; however no comments were received.

Regulatory Notices: Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit *http://dms.dot.gov.*

Regulatory Evaluation

This regulation involves a foreign affairs function of the United States and therefore Executive Order 12866 does not apply and evaluation under the Department of Transportation's Regulatory Policies and Procedures is not required.

Regulatory Flexibility Act Determination

I certify this regulation will not have a significant economic impact on a substantial number of small entities. The St. Lawrence Seaway Tariff of Tolls primarily relate to commercial users of the Seaway, the vast majority of whom are foreign vessel operators. Therefore, any resulting costs will be borne mostly by foreign vessels.

Environmental Impact

This regulation does not require an environmental impact statement under the National Environmental Policy Act (49 U.S.C. 4321, et reg.) because it is not a major federal action significantly affecting the quality of the human environment.