International Branch, ANM–116, FAA, Transport Airplane Directorate. The request shall be forwarded through an appropriate FAA Operations Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116 ACO.

Note 1: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116 ACO.

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on July 30, 1999.

D.L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 99–20326 Filed 8–5–99; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 113

RIN 1515–AC44

Importation and Entry Bond Conditions Regarding Other Agency Documentation Requirements

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

ACTION: Notice of proposed rulemaking.

SUMMARY: This document proposes to amend the Customs Regulations with regard to the basic importation and entry bond condition under which, if merchandise is conditionally released to the principal named in the bond, the principal agrees to furnish Customs with any document or evidence as required by law or regulation. The proposed amendment would extend this requirement, and consequently the potential liability for payment of liquidated damages for a breach of the bond condition, to documents and evidence submitted to other Government agencies under laws and regulations of those other agencies.

DATES: Comments must be received on or before October 5, 1999.

ADDRESSES: Written comments (preferably in triplicate) may be addressed to the Regulations Branch, Office of Regulations and Rulings, U.S. Customs Service, 1300 Pennsylvania Avenue, 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, Penalties Branch, Office of Regulations and Rulings (202–927–2344).

SUPPLEMENTARY INFORMATION:

Background

Section 113.62 of the Customs Regulations (19 CFR 113.62) sets forth the conditions that are incorporated by reference in a basic importation and entry bond (on Customs Form 301) that must be on file with Customs when merchandise is imported and entered in the United States. Those conditions involve the agreements on the part of the obligors under the bond (that is, the principal and/or the surety) to take specific actions required by statute or regulation in connection with the importation/entry process and to pay liquidated damages as a consequence of a default on any agreement in a bond condition.

Paragraph (c) of § 113.62 concerns the agreement to produce documents and evidence. This regulatory text provides that ''[i]f merchandise is released conditionally to the principal before all required documents or other evidence is produced, the principal agrees *to furnish Customs* with any document or evidence as required by law or regulation, and within the time specified by law or regulations'' (emphasis added). Since this bond condition refers only to documents or other evidence required to be furnished to Customs, it would not apply to documents and other evidence that are required by law or regulation to be submitted to another Government agency. Under paragraph (l)(1) of § 113.62, if the principal defaults on the paragraph (c) agreement, the obligors (that is, the principal and surety, jointly and severally) agree to pay liquidated damages in an amount generally equal to the value of the merchandise involved in the default or another amount that may vary depending on the nature of the merchandise or the terms of the specific substantive law or regulation at issue.

Basis for the Proposed Regulatory Change

On January 13, 1999, the Farm Service Agency (FSA) of the Department of Agriculture published in the **Federal Register** (64 FR 2152) a proposed rule to amend Part 782 of the FSA Regulations (7 CFR part 782), which pertains to the end-use certificate program. The end-use certificate program was established pursuant to section 321(f) of the North American Free Trade Agreement Implementation Act (Public Law 103–182, 107 Stat. 2057), which is codified at 19 U.S.C. 3391(f). The program applies to wheat or barley imported into the United States from any foreign country or instrumentality thereof that, as of April 8, 1994, required end-use certificates for imports of U.S.-produced wheat or barley. The purpose of the program is to ensure that foreign agricultural commodities do not benefit from U.S. export programs (*see* H. Rep. 103–361, 103d Cong., 1st Sess., at 68). The regulations under the program, which were promulgated by the FSA in consultation with Customs as required by the statute, currently affect only wheat originating in Canada (see 7 CFR 782.10(b)).

The amendments proposed by the FSA in the January 13, 1999 notice would affect §§ 782.2 and 782.12 (7 CFR 782.2 and 782.12), which set forth, respectively, the definitions that apply for purposes of Part 782 and the requirements for completing and filing the end-use certificate for imports of wheat originating in Canada. Specifically, the proposed regulatory changes would: (1) Amend the definition of ''importer'' to refer to the party qualifying as importer of record under 19 U.S.C. 1484(a); (2) reduce the time period for submission of the end-use certificate (form FSA–750) to the FSA from ''within 15 workdays following the date of entry'' to ''within 10 workdays following the date of entry or release'; and (3) add several data elements to be set forth on the form FSA–750.

In addition to a discussion of the proposed regulatory amendments, the background portion of the January 13, 1999, FSA notice contains the following statement: ''The U.S. Customs Service has informed the Department of Agriculture officials that it will be amending the provisions of their basic import bond to allow for the assessment of damages if there is a failure to provide the End-Use Certificate in the time period provided by FSA.'' This statement resulted from discussions that Customs personnel had with FSA personnel regarding ways to improve the administration and enforcement of the end-use certificate program, consistent with the statutory consultative mandate set forth in the statute and reflected in the FSA regulations (see 7 CFR 782.3), and reflected the fact that the text of present paragraph (c) of § 113.62 technically does not apply to the end-use certificate because it is not furnished to Customs but rather is submitted to the FSA.

Nature and Scope of the Proposed Regulatory Change

Based on the above, Customs is proposing in this document to revise paragraph (c) of § 113.62 to ensure that it will cover documents and other evidence required in connection with the importation/entry process that are prescribed by, and submitted to, Government agencies other than Customs. Although the need for this proposal arose in the specific context of the FSA end-use certificate program, Customs has drafted the proposed new regulatory language in broad terms because Customs believes that the basic principle at issue should be applicable to importation/entry-related requirements of all Government agencies.

Comments

Before adopting this proposed regulation 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 normal business days between the hours of 9 a.m. and 4:30 p.m. at the Regulations Branch, Office of Regulations and Rulings, U.S. Customs Service, 1300 Pennsylvania Avenue, NW., 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 amendment, if adopted, will not have a significant economic impact on a substantial number of small entities. The proposed regulatory amendment will not require any additional action on the part of the public but rather is intended to facilitate Customs enforcement efforts involving existing import requirements under other Government agency laws and regulations. Accordingly, the proposed amendment is 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.

Drafting Information

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

List of Subjects in 19 CFR Part 113

Bonds, Customs duties and inspection, Imports, Reporting and recordkeeping requirements, Surety bonds.

Proposed Amendments to the Regulations

For the reasons stated above, it is proposed to amend Part 113 of the Customs Regulations (19 CFR part 113) as set forth below.

PART 113—CUSTOMS BONDS

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

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

* * * * *

2. Section 113.62(c) is revised to read as follows:

§ 113.62 Basic importation and entry bond conditions.

* * * * *

(c) *Agreement to produce documents and evidence.* If merchandise is released conditionally to the principal before production of all documents or other evidence required by a law or regulation administered by Customs or another government agency, the principal agrees to furnish Customs or the other government agency with any such document or other evidence as required by, and within the time specified in, such law or regulation.

* * * * *

Raymond W. Kelly,

Commissioner of Customs.

Approved: June 17, 1999.

John P. Simpson,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 99–20248 Filed 8–5–99; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 314

[Docket No. 85N–0214]

180–Day Generic Drug Exclusivity for Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations governing 180-day generic drug exclusivity under the Federal Food, Drug, and Cosmetic Act (the act). The proposed rule clarifies existing eligibility requirements for abbreviated new drug application (ANDA) sponsors and describes new eligibility requirements. The proposed changes to the regulations are necessary because of recent court decisions invalidating portions of FDA's current regulations. The proposed regulations are intended to permit the prompt entry of generic drug products into the market while maintaining the incentive of market exclusivity for generic drug manufacturers.

DATES: Submit written comments by November 4, 1999. Submit written comments on the information collection requirements by September 7, 1999. See section VIII of this document for the effective date of a final rule based on this document.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written comments on the information collection requirements to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Virginia G. Beakes, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the Hatch-Waxman Amendments) created section 505(j) of the act (21 U.S.C. 355(j)). Section 505(j) established the ANDA approval process, which allows a generic version of a previously approved innovator drug to be approved without submission of a full new drug application (NDA). An ANDA refers to a previously approved new drug application (the ''listed drug'') and relies upon the agency's finding of safety and effectiveness for that drug product.

Innovator drug applicants must include in an NDA information about patents for the drug product that is the subject of the NDA. FDA publishes this patent information as part of the agency's publication ''Approved Drug