

(3) The exporter has paid, or committed to pay, all export charges due in accordance with the volume, export price, and export charge rate or rates, if any, as calculated under an international agreement entered into by the country of export and the United States and consistent with the export charge determinations published by the Under Secretary for International Trade of the Department of Commerce.

(iv) Any substantiating documentation that supports an importer's softwood lumber declaration is subject to the recordkeeping provisions set forth in part 163 of title 19 to the CFR.

(d) *Entry requirements for home packages and kits—(1) Declaration and required documentation.* Home packages and kits as described in section 804(c)(7)(A)(i) through (iv) of the Title VIII of the Tariff Act of 1930, as amended (19 U.S.C. 1202 *et seq.*) are not subject to the entry requirements set forth in paragraph (c) of this section. However, the importer is required to make a declaration pursuant to section 804(c)(7)(B) and is required to retain and produce upon demand by CBP, the following documentation:

(i) A copy of the appropriate home design, plan, or blueprint matching the customs entry in the United States.

(ii) A purchase contract from a retailer of home kits or packages signed by a customer not affiliated with the importer.

(iii) A listing of all parts in the package or kit being entered into the United States that conforms to the home design, plan, or blueprint for which such parts are being imported.

(iv) If a single contract involved multiple entries, an identification of all the items required to be listed under paragraph (d)(1)(iii) of this section that are included in each individual shipment.

(2) *Records and retention.* There is no requirement to present physical copies of the softwood lumber home packages and kits documentation to CBP at the time of filing the entry summary; however copies must be maintained in accordance with the applicable recordkeeping provisions set forth in part 163 of title 19 to the CFR.

(e) *Other softwood lumber entry requirements.* Other entry requirements may be applicable to certain imports of softwood lumber or softwood lumber from Canada. Importers are advised to refer to § 12.140 (19 CFR 12.140) of this chapter for information regarding applicability and entry requirements.

## PART 163—RECORDKEEPING

- 4. The authority citation for part 163 continues to read as follows:

**Authority:** 5 U.S.C. 301; 19 U.S.C. 66, 1484, 1508, 1509, 1510, 1624.

- 5. The Appendix to part 163 is amended by adding, in numerical order, a listing for § 12.142 under section IV to read as follows:

### Appendix to Part 163—Interim (a)(1)(A) List

\* \* \* \* \*

#### § 12.142 Softwood Lumber Importer Declaration Supporting Documentation, Softwood Lumber Home Packages and Kits Documentation.

\* \* \* \* \*

**W. Ralph Basham,**

Commissioner, U.S. Customs and Border Protection.

Approved: August 20, 2008.

**Timothy E. Skud,**

Deputy Assistant Secretary of the Treasury.

[FR Doc. E8-19641 Filed 8-22-08; 8:45 am]

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## DEPARTMENT OF HOMELAND SECURITY

### Bureau of Customs and Border Protection

## DEPARTMENT OF THE TREASURY

### 19 CFR Part 141

[Docket No. USCBP-2008-0062]

RIN 1505-AB96; CBP Dec. 08-31

### First Sale Declaration Requirement

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

**ACTION:** Interim rule; solicitation of comments.

**SUMMARY:** This document establishes an importer declaration requirement pursuant to section 15422(a) of the Food, Conservation, and Energy Act of 2008 to assist Customs and Border Protection (CBP) in gathering information for all goods entered for consumption or withdrawn from warehouse for consumption on the transaction valuation of goods imported into the United States. Effective for a one-year period beginning August 20, 2008, all importers will be required to provide a declaration to CBP at the time of filing a consumption entry when, in a series of sequential sales, the transaction value of the imported

merchandise is determined on the basis of the “first or earlier sale” of goods—the first sale in which the goods are “sold for exportation to the United States” or any other sale earlier than the last sale prior to the introduction of the merchandise into the United States. CBP will then report the frequency of the use of the “first sale” rule and other associated data to the International Trade Commission (ITC) on a monthly basis.

**DATES:** This interim rule is effective on August 20, 2008. Comments must be received on or before October 24, 2008.

**ADDRESSES:** You may submit comments, identified by docket number, by one of the following methods:

• *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments via docket number USCBP-2008-0062.

• *Mail:* Trade and Commercial Regulations Branch, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., (Mint Annex), Washington, DC 20229.

*Instructions:* All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the “Public Participation” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

**Docket:** For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>. Submitted comments may also be inspected on regular business days between the hours of 9 a.m. and 4:30 p.m. at the Trade and Commercial Regulations Branch, Office of International Trade, Regulations and Rulings, Customs and Border Protection, 799 9th Street, NW. (5th Floor), Washington, DC. Arrangements to inspect submitted comments should be made in advance by calling Mr. Joseph Clark at (202) 572-8768.

**FOR FURTHER INFORMATION CONTACT:** Monika Brenner, Valuation and Special Programs Branch, Regulations and Rulings, Office of International Trade, (202) 572-8835.

### SUPPLEMENTARY INFORMATION:

#### Public Participation

Interested persons are invited to participate in this rulemaking by submitting written data, views, or arguments on all aspects of the interim rule. Customs and Border Protection

(CBP) also invites comments that relate to the economic, environmental, or federalism effects that might result from this interim rule. Comments that will provide the most assistance will reference a specific portion of the interim rule, explain the reason for any recommended change, and include data, information, or authority that support such recommended change.

## Background

The value of merchandise imported into the United States is determined primarily under transaction value which the U.S. value law, set forth in 19 U.S.C. 1401a, defines as “the price actually paid or payable for the merchandise when sold for exportation to the United States” plus specified additions to that amount. 19 U.S.C. 1401a(b)(1). The phrase “sold for exportation to the United States” is not defined in 19 U.S.C. 1401a, nor in the implementing regulations set forth in part 152 of title 19 of the Code of Federal Regulations (19 CFR part 152).

### Notice of Proposed Interpretation

On January 24, 2008, CBP published in the **Federal Register** (73 FR 4254) a notice informing interested parties that CBP proposed a new interpretation of the expression “sold for exportation to the United States” for purposes of applying the transaction value method of valuation in a series of sales importation scenario. Under this proposed new interpretation in a transaction involving a series of sales, the price paid in the last sale occurring prior to the introduction of the goods into the United States, instead of an earlier sale, would be considered the price actually paid or payable for the imported goods when sold for exportation to the United States. CBP is withdrawing the notice of proposed interpretation.

### Food, Conservation, and Energy Act of 2008

On May 22, 2008, Congress passed the Food, Conservation, and Energy Act of 2008 (the “Act”), Public Law 110–234, 122 Stat. 1547 (19 U.S.C. 1484 note). Section 15422 of the Act, in pertinent part, requires:

- CBP must collect a declaration as to whether the transaction value of the imported merchandise is determined on the basis of the price paid in the first or earlier sale occurring prior to the introduction of the merchandise into the United States.
- CBP must provide the collected information to the ITC on a monthly basis.

- ITC must submit a report to the House Ways and Means Committee and the Senate Finance Committee within 90 days of receipt of CBP’s final monthly report.

- A “sense of Congress” provision advises that CBP not amend its interpretation of “sold for exportation to the United States” for purposes of applying the transaction value of the imported merchandise in a series of sales before January 1, 2011. Beginning on January 1, 2011, CBP may propose to change its interpretation only if CBP: (1) Consults with and provides notice to the committees noted above not less than 180 days prior to proposing a change and not less than 90 days prior to publishing a change; (2) consults with, provides notice to, and takes into consideration views expressed by the Commercial Operations Advisory Committee not less than 120 days prior to proposing a change and not less than 60 days prior to publishing a change; and (3) receives the explicit approval of the Secretary of the Treasury prior to publishing a change. CBP should also take into consideration the ITC report before publishing any change to the expression “sold for exportation to the United States.”

### Required Information on Entry Summary (CBP Form 7501)

In addition to the entry and entry summary information otherwise required for importation into the United States, as per section 484 of the Tariff Act of 1930, as amended (19 U.S.C. 1484), the Act obligates CBP to require that a U.S. importer of merchandise provide a declaration at the time of entry of the merchandise on the entry summary form, CBP Form 7501, as to whether the value of the imported merchandise was determined on the basis of the price paid by the buyer in the “first or earlier sale.”

On June 10, 2008, CBP participated in a teleconference call with members of the Trade Support Network (TSN), a group of private-sector trade representatives that provides CBP with input on the development of Customs Modernization projects. Participants in the call discussed various ways to indicate when customs value is based on the “first sale” on CBP Form 7501. Initially, CBP had considered requiring importers to provide three data elements on CBP Form 7501. During the teleconference, CBP agreed with TSN members that requiring importers to provide as few data elements as possible would be the most efficient and least burdensome manner in which to implement the declaration requirement. CBP has concluded, based upon its

consultation with the TSN, that it will require importers to provide one data element.

In order to implement the above requirement of the Act, importers will be required to insert a single code on CBP Form 7501 at the line-item level, indicating when first sale was used to determine the value of the imported merchandise. An importer will be required to enter an “F” next to the declared value if the value of the merchandise is based on transaction value, and the transaction value of the merchandise is based on the price paid by the buyer in the “first or earlier sale.” This special indicator code will enable CBP to fulfill its information collection obligation under the Act.

### Inapplicability of Notice and Delayed Effective Date Requirements

Pursuant to 5 U.S.C. 553(b)(B) and (d)(3), CBP has determined that it would be impracticable and contrary to the public interest to delay publication of this rule in final form pending an opportunity for public comment and that there is good cause for this interim rule to become effective immediately upon publication. These interim amendments to 19 CFR 141.61(g) conform the regulations to the information collection requirements set forth in section 15422(a) of the Food, Conservation, and Energy Act of 2008, Public Law 110–234, 122 Stat. 1547 (19 U.S.C. 1484 note), which is effective August 20, 2008. These interim amendments inform the public of the procedures necessary to comply with the statutory requirements. For these reasons, pursuant to the provisions of 5 U.S.C. 553(d)(3), CBP finds that there is good cause for dispensing with a delayed effective date.

### Regulatory Flexibility Act and Executive Order 12866

Because no notice of proposed rulemaking is required for this interim rule, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply. Further, these interim amendments do not meet the criteria for a “significant regulatory action” as specified in E.O. 12866.

### Paperwork Reduction Act

The collections of information in this document are contained in § 141.61(g) (19 CFR 141.61(g)). This information is used by CBP to fulfill its information collection obligations under section 15422(a) of the Food, Conservation, and Energy Act of 2008, Public Law 110–234, 122 Stat. 1547 (19 U.S.C. 1484 note), which mandates that CBP require a U.S. importer of merchandise to

provide information at the time of entry of the merchandise on the entry summary form, CBP Form 7501, as to whether the value of the imported merchandise was determined on the basis of the price paid by the buyer in the “first or earlier sale.” The likely respondents are business organizations including importers and brokers. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by OMB. This collection of information falls under the previously approved collection 1651–0022 for the Entry Summary, CBP Form 7501.

#### **Signing Authority**

This document is being issued in accordance with § 0.1(a)(1) of title 19 of the Code of Federal Regulations (19 CFR 0.1(a)(1)) pertaining to the authority of the Secretary of the Treasury (or his/her delegate) to approve regulations related to certain customs revenue functions.

#### **List of Subjects in 19 CFR Part 141**

Customs duties and inspection, Entry of merchandise, Reporting and recordkeeping requirements.

#### **Amendments to the Regulations**

- For the reasons stated above, part 141 of title 19 of the Code of Federal Regulations (19 CFR part 141) is amended as set forth below.

#### **PART 141—ENTRY OF MERCHANDISE**

- 1. The general authority citation for part 141 continues to read, and the specific authority for § 141.16 is added, to read as follows:

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

\* \* \* \* \*

Section 141.61 also issued under sec. 15422(a), Pub. L. 110–234, 122 Stat. 1547 (19 U.S.C. 1484 note) and 19 U.S.C. 1401a.

\* \* \* \* \*

- 2. Section 141.61 is amended by adding a new paragraph (g) to read as follows:

#### **§ 141.61 Completion of entry and entry summary documentation.**

\* \* \* \* \*

(g) *Declaration of value.* Pursuant to section 15422(a) of the Food, Conservation, and Energy Act of 2008 (Pub. L. 110–234), for all goods entered for consumption or withdrawn from warehouse for consumption from August 20, 2008 through August 19, 2009, an importer of merchandise must enter an “F” next to the declared value on CBP Form 7501, or the electronic filing equivalent, when the declared transaction value of the imported

merchandise is determined on the basis of the price paid by the buyer in a sale occurring earlier than the last sale prior to the introduction of the merchandise into the United States.

**W. Ralph Basham,**

*Commissioner, U.S. Customs and Border Protection.*

Approved: August 20, 2008.

**Timothy E. Skud,**

*Deputy Assistant Secretary of the Treasury.*

[FR Doc. E8–19640 Filed 8–20–08; 4:15 pm]

**BILLING CODE 9111–14–P**

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#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

#### **Food and Drug Administration**

#### **21 CFR Parts 16, 610, 640, 812, 814, 822, and 860**

[Docket No. FDA–2008–N–0423]

#### **FDA Regulations; Technical Amendment**

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

**ACTION:** Final rule; technical amendment.

**SUMMARY:** The Food and Drug Administration (FDA) is amending a regulatory hearing process regulation to correct an inaccurate citation, and regulations pertaining to biological products to correct two typographical errors. FDA is also amending certain medical device regulations to include references to and mailing address information for the Center for Biologics Evaluation and Research (CBER), Center for Drug Evaluation and Research (CDER), and Center for Devices and Radiological Health (CDRH). This action is being taken to ensure the accuracy of FDA's regulations.

**DATES:** This rule is effective August 25, 2008.

#### **FOR FURTHER INFORMATION CONTACT:**

Denise Sánchez, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is amending 21 CFR 16.1 to correct an inaccurate citation and is amending 21 CFR 610.51 and 21 CFR 640.53 to correct typographical errors.

FDA is also amending its medical device regulations in 21 CFR 812, 814, and 860 to include references to and mailing addresses for CBER and CDER,

and 21 CFR 822.8 to correct an inadvertent omission of the mailing address for CDRH. Submissions regarding a medical device must be sent to the address of the appropriate center that has regulatory responsibility for the medical device. Therefore, FDA is updating these regulations to include address information for all appropriate centers.

Publication of this document constitutes final action under the Administrative Procedures Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because this amendment to the regulations provides only technical changes to correct an inaccurate citation and typographical errors, and to update mailing addresses and other information, and is nonsubstantive.

#### **List of Subjects**

**21 CFR Part 16**

Administrative practice and procedure.

**21 CFR Part 610**

Biologics, Labeling, Reporting and recordkeeping requirements.

**21 CFR Part 640**

Blood, Labeling, Reporting and recordkeeping requirements.

**21 CFR Part 812**

Health records, Medical devices, Medical research, Reporting and recordkeeping requirements.

**21 CFR Part 814**

Administrative practice and procedure, Confidential business information, Medical devices, Medical research, Reporting and recordkeeping requirements.

**21 CFR Part 822**

Medical devices, Reporting and recordkeeping requirements.

**21 CFR Part 860**

Administrative practice and procedure, Medical devices.

- Therefore, under the Federal Food, Drug, and Cosmetic Act, and Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 16, 610, 640, 812, 814, 822, and 860 are amended as follows:

#### **PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION**

- 1. The authority citation for 21 CFR part 16 continues to read as follows: