

# Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## DEPARTMENT OF HOMELAND SECURITY

### Bureau of Customs and Border Protection

## DEPARTMENT OF THE TREASURY

### 19 CFR Parts 19 and 144

[USCBP–2007–0080]

RIN 1505–AB85

### Class 9 Bonded Warehouse Procedures

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

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** This document proposes amendments to title 19 of the Code of Federal Regulations, with respect to the requirements applicable to the operation of Class 9 bonded warehouses, which are also known as “duty-free sales enterprises” or “duty-free stores.” The proposed amendments would extend the blanket withdrawal procedure for Class 9 bonded warehouses to cover vessel supplies under certain circumstances and expand and create a uniform time period for Class 9 proprietors to file an entry, provide written confirmation of certain shortages, overages, and damages, and to pay duties, taxes, and interest on overages and shortages. In addition, the proposed amendments would permit Class 9 warehouses to utilize technological systems more effectively. The proposed changes would facilitate the efficient operation of Class 9 warehouses and also ensure adequate records are maintained for U.S. Customs and Border Protection (“CBP”) trade enforcement purposes.

**DATES:** Comments must be received on or before March 17, 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–2007–0080.

- Mail: Trade and Commercial Regulations Branch, Regulations and Rulings, 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 during regular business days between the hours of 9 a.m. and 4:30 p.m. at the Trade and Commercial Regulations Branch, Regulations and Rulings, U.S. Customs and Border Protection, 799 9th Street, NW. (5th Floor), Washington, DC. Arrangements to inspect submitted comments should be made in advance by calling Joseph Clark at (202) 572–8768.

**FOR FURTHER INFORMATION CONTACT:** Gary Rosenthal, Cargo Control Branch, Office of Field Operations, (202) 344–2673.

### 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 proposed rule. CBP also invites comments that relate to the economic, environmental, or federalism effects that might result from this proposed rule. Comments that will provide the most assistance to CBP will reference a specific portion of the proposed rule, explain the reason for any recommended change, and include data, information, or authority that support such recommended change. See **ADDRESSES** above for information on how to submit comments.

## Background

Section 1555 of title 19 of the United States Code (19 U.S.C. 1555) sets forth provisions governing the establishment and operation of customs bonded warehouses. Section 1555(b) provides for a type of bonded warehouse, Class 9, also called a “duty-free sales enterprise” or “duty-free store.” As defined in § 1555(b)(8)(D), duty-free sales enterprise means a person that sells, for use outside the customs territory, duty-free merchandise that is delivered from a bonded warehouse to an airport or other exit point for exportation by, or on behalf of, individuals departing from the customs territory of the United States. The regulations implementing § 1555(b), and which govern the operation of duty-free stores, are found within parts 19 and 144 of title 19 of the Code of Federal Regulations (19 CFR parts 19 and 144).

U.S. Customs and Border Protection (“CBP”) proposes to amend certain regulations governing the operation of duty-free stores in order to align the regulations with actual business practices and the use of modern technologies. The amendments proposed in this document are intended to facilitate the operation of duty-free stores in a technological environment by streamlining outdated processes and requirements while ensuring adequate records are maintained for audit purposes. In addition, this document proposes non-substantive amendments to §§ 19.6, 19.12, 19.36, and 144.37 of the CFR to reflect the nomenclature changes effected by the transfer of CBP to the Department of Homeland Security.

### Explanation of Amendments

Sections 19.6, 19.12, 19.36, and 144.37 of title 19 of the CFR (19 CFR 19.6, 19.12, 19.36, and 144.37) are proposed to be amended as described below. Some of these provisions involve general rules for all bonded warehouses, but CBP is proposing exceptions to these general procedures for duty-free stores or Class 9 warehouses. Class 9 warehouses are more akin to retail establishments since they cater to the traveling public and undertake many sales transactions in a given day. Therefore, the exceptions to the general procedures proposed in this document are intended to eliminate unnecessary requirements for duty-free stores

without changing the requirements applicable to the other classes of bonded warehouses.

### **I. Section 19.6 Deposits, Withdrawals, Blanket Permits To Withdraw and Sealing Requirements**

Section 19.6 of title 19 of the CFR (19 CFR 19.6) describes the requirements for depositing merchandise into or withdrawing merchandise from a warehouse, including the requirements pertaining to blanket permits to withdraw. Under § 19.6(d), such blanket permits to withdraw are currently permitted only when goods are delivered within the same port from which the goods are withdrawn. Therefore, the regulation does not currently permit blanket permits for withdrawal to be used in situations where vessel supplies are delivered from a warehouse to a cruise ship at a nearby port if that port is different from the warehouse port. Rather, in such cases, approval from both ports is required for withdrawal.

This notice proposes to amend § 19.6(d) in order to allow the appropriate Director, Field Operations, to extend the blanket withdrawal procedure for vessel supplies in situations where the Class 9 warehouse and destination port are within that Director's authority. To this end, the new blanket withdrawal procedure for a withdrawal of vessel supplies from a Class 9 warehouse would allow, upon a showing of good cause and with the written approval of the appropriate Director, Field Operations, the transportation in bond of the vessel supplies from the port where the warehouse is located to the port where the vessel is located. This new procedure would permit subject merchandise to be transported in a more timely and efficient manner.

### **II. Section 19.12 Inventory Control and Recordkeeping System**

Section 19.12 of title 19 of the CFR (19 CFR 19.12) provides for inventory control and recordkeeping systems. This notice proposes to amend § 19.12(d)(3), which sets forth the requirements for the accounting of merchandise in bonded warehouses and for the reporting of inventory theft, shortages, overages, and damages to set forth specific rules for Class 9 warehouses. The regulation currently requires the proprietor to immediately bring to the attention of the port director any theft or suspected theft or overage or any extraordinary shortages or damage, and to provide confirmation in writing within five business days after the shortage, overage, or damage has been

so reported. The regulation additionally provides that entries for warehouse must be filed for all overages within five business days of the date of discovery. The applicable duties, taxes, and interest on thefts and shortages so reported must be paid within 20 calendar days following the end of the calendar month in which the shortage was discovered.

According to the International Association of Airport Duty Free Stores ("IAADFS"), five business days provides insufficient time for Class 9 proprietors to provide the required written confirmation or to file the appropriate entries for routine overages. Accordingly, in order to provide adequate time to comply with the reporting and filing requirements, this document proposes to modify § 19.12(d)(3) so as to afford the Class 9 proprietor with 20 calendar days to provide the required written confirmation and to require that an entry for warehouse be filed for all overages by the person with the right to make entry within 20 calendar days of the date of discovery. As with the current regulation, applicable duties, taxes, and interest on thefts and shortages so reported will be required to be paid by the Class 9 proprietor within 20 calendar days following the end of the calendar month in which the shortage was discovered.

This notice also proposes to amend § 19.12(h)(2), which sets forth the information required for the annual reconciliation report, to set forth special rules for Class 9 warehouses. The regulation currently provides that the report must contain the company name, address of the warehouse, class of warehouse, date of inventory or information on cycle counts, a description of merchandise for each entry or unique identifier, quantity on hand at the beginning of the year, cumulative receipts and transfers (by unit), quantity on hand at the end of the year, and cumulative positive and negative adjustments (by unit) made during the year.

Requiring this level of detail on the annual reconciliation report for Class 9 proprietors creates a large volume of paperwork for the operators who are responsible for thousands of open warehouse entries each year. In addition, the current regulation requires that operators approved as integrated locations provide the details of all transactions by location, in effect requiring a separate annual report for each integrated location. Class 9 proprietors are having difficulty complying with the current system because summarizing every transaction

for each unit in every entry is burdensome given the volume of transactions and because units transferred under the FIFO (first in, first out) accounting system are not assigned an entry number until they are sold or are otherwise disposed of. Therefore, the information required for the annual reconciliation report for transferred units may not even be available.

Accordingly, this notice proposes to amend § 19.12(h)(2) to provide for a reduced reporting requirement for Class 9 proprietors in cases where the proprietor successfully demonstrates, by application to the appropriate CBP port director, that shortages will be reported within 20 calendar days of discovery. If such application is approved by the port director, the Class 9 proprietor would be permitted to submit a report that sets forth the company name; address of the warehouse; class of warehouse; dates when physical inventories and cycle counts occur; dates when resulting shortages and overages are reported to CBP; and a listing of all entries open at the beginning of the year, added during the year, and closed during the year. In such cases, it is believed that this level of information would both address the above-referenced reporting concerns and ensure that CBP is provided with the information required for enforcement purposes.

### **III. Section 19.36 Requirements for Duty-Free Store Operations**

Section 19.36 of title 19 of the CFR (19 CFR 19.36) sets forth the requirements for duty-free store operations, including guidance on the type of merchandise permitted in the bonded sales or crib area of a Class 9 warehouse. Under § 19.36(e), domestic merchandise and merchandise previously entered or withdrawn for consumption may be brought into the bonded sales or crib area of a Class 9 warehouse for display or sale, and in the case of a crib, for delivery to purchasers only if the merchandise is identified or marked "DUTY-PAID" or "U.S.-ORIGIN", or similar markings, such that CBP officers can easily distinguish conditionally duty-free merchandise from other merchandise in the sales or crib area.

CBP notes, however, that modern technology permits duty-free store proprietors to electronically scan and read merchandise bar codes that contain detailed product information. Therefore, this notice proposes to amend § 19.36(e) so as to provide an alternative to marking merchandise for those proprietors of Class 9 warehouses who maintain an electronic system capable of immediately identifying "DUTY-

PAID” or “U.S.-ORIGIN” merchandise. In addition, it is proposed to eliminate the requirement that conditionally duty-free merchandise be physically separated from other merchandise in the sales or crib area for those Class 9 warehouse proprietors who can immediately identify the duty status of goods through an electronic system.

#### IV. Section 144.37 Withdrawal for Exportation

Section 144.37 of title 19 of the CFR (19 CFR 144.37) sets forth the procedures for withdrawing merchandise from a warehouse for exportation. Paragraph (h) of this section pertains to Class 9 warehouses. Under § 144.37(h)(2), a sales ticket, in triplicate, must be made out in the name of the purchaser with at least one copy to be retained by the proprietor. However, current technology permits a sales ticket to be reprinted as often as needed and enables duty-free store proprietors to match bags of purchased merchandise with departing customers. In addition, it is noted that the requirement that sales tickets be produced in triplicate is no longer necessary for verification or audit purposes if the proprietor utilizes current technology. Thus, the triplicate paper procedure has been rendered costly, wasteful, and inefficient. Therefore, this notice proposes to amend § 144.37(h)(2) in order to remove the “in triplicate” requirement and to allow the proprietor’s copy to be maintained electronically, provided the port director is satisfied that the proprietor has the technological capability to immediately print the sales ticket upon the request of a CBP officer.

#### Executive Order 12866

This rule is not considered to be a “significant regulatory action” under Executive Order 12866 of September 30, 1993 (58 FR 51735, October 1993). Accordingly, a regulatory assessment is not required.

#### Regulatory Flexibility Act

CBP has prepared this section to examine the impacts of the proposed rule on small entities as required by the Regulatory Flexibility Act (“RFA”, See 5 U.S.C. 601–612). A small entity may be a small business (defined as any independently owned and operated business not dominant in its field that qualifies as a small business per the Small Business Act); a small not-for-profit organization; or a small governmental jurisdiction (locality with fewer than 50,000 people).

According to the IAADFS, there are approximately 25 companies with duty-

free operations in the United States and approximately 15 of them would be considered small businesses. As described elsewhere in this preamble, this rule is expected to result in enhanced efficiency and should lead to uniform operations at customs bonded warehouses.

Thus, while the number of small entities affected would be considered substantial, the economic impacts, while important and beneficial, would not rise to the level of a “significant economic impact.” CBP thus certifies that the proposed amendments will not have a significant economic impact on a substantial number of small entities. CBP welcomes comments on this certification. Comments regarding impacts to small entities may be submitted by any of the methods described under the ADDRESSES section of this document.

#### Paperwork Reduction Act

The collections of information in this document are contained in §§ 19.6, 19.12, 19.36, and 144.37. This information is required and will be used by CBP to ensure that merchandise that was intended for exportation from duty-free stores was accounted for and was exported in accordance with law. This notice of proposed rulemaking is intended to facilitate the operation of duty-free stores in a technological environment by streamlining outdated paper accounting processes and requirements with electronic equivalents while ensuring that adequate records are maintained for audit purposes. The likely respondents are Class 9 proprietors.

Although this notice of proposed rulemaking is intended to facilitate the efficient operation of Class 9 warehouses, the resulting paperwork implications are expected to be minor. As the burden hours associated with the collections of information contained in this notice of proposed rulemaking are not substantively changed, the Office of Management and Budget has already approved the collections of information in accordance with the requirements of the Paperwork Reduction Act (44 U.S.C. 3507) under control numbers 1651–0003 for bonded warehouse proprietor’s submissions and 1651–0041 concerning the establishment of bonded warehouses and other bonded warehouse regulations.

#### Signing Authority

This document is being issued in accordance with § 0.1(a)(1) of the CBP 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

##### 19 CFR Part 19

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

##### 19 CFR Part 144

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

#### Proposed Amendments to the CBP Regulations

It is proposed to amend parts 19 and 144 of title 19 of the Code of Federal Regulations (19 CFR parts 19 and 144) as set forth below.

### PART 19—CUSTOMS WAREHOUSES, CONTAINER STATIONS, AND CONTROL OF MERCHANDISE THEREIN

1. The general authority citation and specific authority citations for part 19 continue to read as follows:

**Authority:** 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States), 1624;

\* \* \* \* \*

Section 19.6 also issued under 19 U.S.C. 1555;

\* \* \* \* \*

Sections 19.35–19.39 also issued under 19 U.S.C. 1555;

\* \* \* \* \*

2. In § 19.6:

a. In paragraph (a)(1), the first sentence is amended by removing the word “Customs” and, in its place, adding the term “CBP”; the second and last sentences are amended by removing the word “shall” each place it appears and adding the word “will” in its place; and the fourth sentence is amended by removing the word “shall” and, in its place, adding the word “must”.

b. Paragraphs (b)(1), (d)(4), and (d)(5) are amended by removing the word “Customs” each place it appears and, in its place, adding the term “CBP”; and by removing the word “shall” each place it appears and, in its place, adding the word “must”.

c. Paragraph (b)(2) is amended by removing the word “Customs” each place it appears and, in its place, adding the term “CBP”.

d. Paragraph (c) is amended by removing the word “Customs” each place it appears and, in its place, adding the term “CBP”; and by removing the

word “shall” and, in its place, adding the word “will”.

e. Paragraph (d)(1)(i)(A) is amended by removing the term “Customs territory” and, in its place, adding the term “customs territory”.

f. In paragraph (d)(2), the first and second sentences are amended by removing the word “Customs” each place it appears and, in its place, adding the term “CBP” and by removing the word “shall” each place it appears and, in its place, adding the term “must”; the third, fourth, fifth, sixth, and seventh sentences are amended by removing the word “shall” each place it appears and, in its place, adding the term “must”; and the last sentence of the paragraph is amended by removing the word “shall” and, in its place, adding the word “will” and by removing the phrase “without Customs permit” and, in its place, adding the phrase “without a CBP permit”.

g. Paragraph (d)(3) is amended by removing the word “shall” each place it appears and, in its place, adding the word “must”.

h. In paragraph (e), the first sentence is amended by removing the word “Customs” each place it appears and, in its place, adding the term “CBP”; the second sentence is amended by removing the word “shall” and, in its place, adding the term “will” and by removing the word “Customs” and, in its place, adding the term “CBP”; and the last sentence of the paragraph is amended by removing the word “shall” and, in its place, adding the word “must”.

i. Paragraph (d)(1)(ii) is revised to read as follows:

**§ 19.6 Deposits, withdrawals, blanket permits to withdraw and sealing requirements.**

\* \* \* \* \*

(d) \* \* \*

(1) \* \* \*

(ii) Blanket permits to withdraw may be used only for delivery at the port where withdrawn and not for transportation in bond to another port, except blanket permits to withdraw may be used for a withdrawal for transportation to another port by a duty-free sales enterprise which meets the requirements for exemption as stated in § 144.34(c) of this chapter or for a withdrawal from a Class 9 warehouse for transportation in bond to another port for vessel supplies when expressly authorized in writing by the appropriate Director, Field Operations, provided that both the Class 9 warehouse and port of destination are under that Director’s authority. Blanket permits to withdraw may not be used for delivery

to a location for retention or splitting of shipments under the provisions of § 18.24 of this chapter. A withdrawer who desires a blanket permit must state on the warehouse entry, or on the warehouse entry/entry summary when used as an entry, that “Some or all of the merchandise will be withdrawn under blanket permit per § 19.6(d), CBP Regulations.” CBP’s acceptance of the entry will constitute approval of the blanket permit. A copy of the entry will be delivered to the proprietor, whereupon merchandise may be withdrawn under the terms of the blanket permit. The permit may be revoked by the port director in favor of individual applications and permits if the permit is found to be used for other purposes, or if necessary to protect the revenue or properly enforce any law or regulation CBP is charged with administering. Merchandise covered by an entry for which a blanket permit was issued may be withdrawn for purposes other than those specified in this paragraph if a withdrawal is properly filed as required in subpart D, part 144, of this chapter.

\* \* \* \* \*

**3. In § 19.12:**

a. Paragraph (a)(1) is amended by removing the word “Customs” each place it appears and, in its place, adding the term “CBP”; and the word “shall” is removed and the word “must” is added in its place.

b. Paragraphs (a)(3), (d)(2)(ii), (d)(4)(iii), (f)(2), (h)(1), and (h)(3) are amended by removing the word “Customs” each place it appears and, in its place, adding the term “CBP”.

c. Paragraphs (b)(1) and (b)(2) are amended by removing the word “shall” each place it appears and, in its place, adding the word “must”.

d. Paragraphs (c)(1), (c)(3), (d)(1), (d)(2), and (e) are amended by removing the term “Customs entry” each place it appears and, in its place, adding the term “customs entry”.

e. Paragraphs (f)(5), (f)(6), (f)(7), (f)(8), (f)(9), and (i) are amended by removing the word “shall” each place it appears and, in its place, adding the word “must”.

f. Paragraphs (d)(4)(i), (d)(4)(ii), (d)(5), and (f)(1) are amended by removing the word “shall” each place it appears and, in its place, adding the word “must”; and by removing the word “Customs” each place it appears and, in its place, adding the term “CBP”.

g. In paragraph (g), the word “Customs” is removed each place it appears and, in its place, the term “CBP” is added; in the first sentence, “(CF)” is removed; the term “CF 300”

is removed each place it appears and, in its place, the term “CBP Form 300” is added; and the word “shall” is removed and, in its place, the word “must” is added.

h. In paragraph (j), the term “(CF 300)” is removed and, in its place, the term “(CBP Form 300)” is added.

i. Paragraphs (d)(3) and (h)(2) are revised to read as follows:

**§ 19.12 Inventory control and recordkeeping system.**

\* \* \* \* \*

(d) \* \* \*

(3) *Theft, shortage, overage or damage—(i) General.* Except as otherwise provided in paragraph (d)(3)(ii) of this section, any theft or suspected theft or overage or any extraordinary shortage or damage (equal to one percent or more of the value of the merchandise in an entry or covered by a unique identifier; or if the missing merchandise is subject to duties and taxes in excess of \$100) must be immediately brought to the attention of the port director, and confirmed in writing within five business days after the shortage, overage, or damage has been brought to the attention of the port director. An entry for warehouse must be filed for all overages by the person with the right to make entry within five business days of the date of discovery. The responsible party must pay the applicable duties, taxes and interest on thefts and shortages reported to CBP within 20 calendar days following the end of the calendar month in which the shortage is discovered. The port director may allow the consolidation of duties and taxes applicable to multiple shortages into one payment; however, the amount applicable to each warehouse entry is to be listed on the submission and must specify the applicable duty, tax and interest. These same requirements apply when cumulative thefts, shortages or overages under a specific entry or unique identifier total one percent or more of the value of the merchandise or if the duties and taxes owed exceed \$100. Upon identification, the proprietor must record all shortages and overages in its inventory control and recordkeeping system, whether or not they are required to be reported to the port director at the time. The proprietor must also record all shortages and overages as required in the CBP Form 300 or annual reconciliation report under paragraphs (g) or (h) of this section, as appropriate. Duties and taxes applicable to any non-extraordinary shortage or damage and not required to be paid earlier must be reported and submitted to the port director no later than the date the

certification of preparation of CBP Form 300 is due or at the time the certification of preparation of the annual reconciliation report is due, as prescribed in paragraphs (g) or (h) of this section.

(ii) *Class 9 warehouses.* With respect to Class 9 warehouses, any theft or suspected theft or overage or any extraordinary shortage or damage (equal to one percent or more of the merchandise in an entry or covered by a unique identifier; or if the missing merchandise is subject to duties and taxes in excess of \$100) must be immediately brought to the attention of the port director, and confirmed in writing within 20 calendar days after the shortage, overage, or damage has been brought to the attention of the port director. An entry for warehouse must be filed for all overages by the person with the right to make entry within 20 calendar days of the date of discovery. The responsible party must pay the applicable duties, taxes and interest on thefts and shortages reported to CBP within 20 calendar days following the end of the calendar month in which the shortage is discovered. The port director may allow the consolidation of duties and taxes applicable to multiple shortages into one payment; however, the amount applicable to each warehouse entry is to be listed on the submission and must specify the applicable duty, tax and interest. These same requirements apply when cumulative thefts, shortages or overages under a specific entry or unique identifier total one percent or more of the value of the merchandise or if the duties and taxes owed exceed \$100. Upon identification, the proprietor must record all shortages and overages in its inventory control and recordkeeping system, whether or not they are required to be reported to the port director at the time. The proprietor must also record all shortages and overages as required in the CBP Form 300 or annual reconciliation report under paragraphs (g) or (h) of this section, as appropriate. Duties and taxes applicable to any non-extraordinary shortage or damage and not required to be paid earlier must be reported and submitted to the port director no later than the date the certification of preparation of CBP Form 300 is due or at the time the certification of preparation of the annual reconciliation report is due, as prescribed in paragraphs (g) or (h) of this section. Discrepancies found in a Class 9 warehouse with integrated locations as set forth in § 19.35(c) will be the net discrepancies for a unique identifier (see § 19.4(b)(8)(ii) of this part)

such that overages within one sales location will be offset against shortages in another location that is within the integrated location. A Class 9 proprietor who transfers merchandise between facilities in different ports without being required to file a rewarehouse entry in accordance with § 144.34 of this chapter may offset overages and shortages within the same unique identifier for merchandise located in stores in different ports (see § 19.4(b)(8)(ii) of this part).

\* \* \* \* \*

(h) \* \* \*

\* \* \* \* \*

(2) *Information required*—(i) *General.* Except as otherwise provided in paragraph (h)(2)(ii) of this section, the report must contain the company name; address of the warehouse; class of warehouse; date of inventory or information on cycle counts; a description of merchandise for each entry or unique identifier, quantity on hand at the beginning of the year, cumulative receipts and transfers (by unit), quantity on hand at the end of the year, and cumulative positive and negative adjustments (by unit) made during the year.

(ii) *Class 9 warehouses.* If the proprietor of a Class 9 warehouse successfully demonstrates, by application to the appropriate port director, that shortages will be reported within 20 calendar days of discovery, the port director may approve the submission of a report that contains the company name; address of the warehouse; class of warehouse; date of inventory or information on cycle counts; date when resulting shortages and overages are reported to CBP; a description of merchandise for each entry or unique identifier; and a listing of all entries open at the beginning of the year, added during the year, and closed during the year.

(iii) *Multiple facilities.* If the proprietor of a Class 2 or Class 9 warehouse has merchandise covered by one warehouse entry, but stored in multiple warehouse facilities as provided for under § 144.34 of this chapter, the reconciliation report must cover all locations and warehouses of the proprietor at the same port. If the annual reconciliation includes entries for which merchandise was transferred to a warehouse without filing a rewarehouse entry, as allowed under § 144.34, the annual reconciliation must contain sufficient detail to show all required information by location where the merchandise is stored. For example, if merchandise covered by a single entry is stored in warehouses located in 3

different ports, the annual reconciliation should specify individually the beginning and ending inventory balances, cumulative receipts, transfers, and positive and negative adjustments for each location.

\* \* \* \* \*

4. In § 19.36:

a. Paragraphs (a) and (f) are amended by removing the term “Customs territory” each place it appears and, in its place, adding the term “customs territory”.

b. In paragraph (b), the first sentence is amended by removing the word “shall” and, in its place, adding the word “must” and by removing the term “Customs territory” and, in its place, adding the term “customs territory”; the third sentence is amended by removing the term “shall” and, in its place, adding the term “will” and by removing the two references to “Customs” and, in its place, adding the term “CBP”; and the fourth sentence is amended by removing the reference to “Customs” and, in its place, adding the term “CBP”.

c. In paragraph (c), the first and fourth sentences are amended by removing the term “shall” each place it appears and adding the term “must” in its place; and the fifth sentence is amended by removing the term “shall” and, in its place, adding the term “will” and by removing the two references to “Customs” and, in its place, adding the term “CBP”.

d. Paragraph (g) is amended by removing the term “shall” each place it appears and, in its place, adding the term “must”; and by removing the term “Customs” and, in its place, adding the term “CBP”.

e. Paragraph (e) is revised to read as follows:

**§ 19.36 Requirements for duty-free store operations.**

\* \* \* \* \*

(e) *Merchandise eligible for warehousing*—(1) *General.* Only conditionally duty-free merchandise may be placed in a bonded storage area of a Class 9 warehouse. However, domestic merchandise and merchandise which was previously entered or withdrawn for consumption, may be brought into the bonded sales or crib area of a Class 9 warehouse for display and sale, and in the case of a crib, for delivery to purchasers.

(2) *Marking requirement.* Except as provided in paragraph (e)(3) of this section, merchandise must either be identified or marked “DUTY-PAID” or “U.S.-ORIGIN”, or similar markings, as applicable, to enable CBP officers to easily distinguish conditionally duty-

free merchandise from other merchandise in the sales or crib area.

(3) *Exception to marking requirement.* If the proprietor has an electronic inventory system capable of immediately identifying other merchandise from conditionally duty-free merchandise, the proprietor need not separate domestic merchandise and merchandise which was previously entered or withdrawn for consumption from conditionally duty-free merchandise or mark the merchandise.

\* \* \* \* \*

## PART 144—WAREHOUSE AND REWAREHOUSE ENTRIES AND WITHDRAWALS

5. The general authority citation and specific authority citation for part 144 continue to read as follows:

**Authority:** 19 U.S.C. 66, 1484, 1557, 1559, 1624.

\* \* \* \* \*

Section 144.37 also issued under 19 U.S.C. 1555, 1562.

6. In § 144.37:

a. Paragraph (a) is amended by removing the word “shall” each place it appears and, in its place, adding the word “must”; and by removing the word “Customs” each place it appears and, in its place, adding the term “CBP”.

b. Paragraphs (b)(1), (f), and (h)(3) are amended by removing the word “shall” each place it appears and, in its place, adding the word “must”.

c. In paragraph (b)(2), the first sentence is amended by removing the word “shall” and, in its place, adding the word “must” and by removing the reference to “Customs” and, in its place, adding the term “CBP”; the second and third sentences are amended by removing the word “shall” each place it appears and, in its place, adding the word “will”; and the last sentence is amended by removing the word “shall” and, in its place, adding the word “must”.

d. Paragraph (d) is amended by removing the word “Customs” each place it appears and, in its place, adding the term “CBP”; and by removing the word “shall” each place it appears and, in its place, adding the word “must”.

e. Paragraphs (h)(2) introductory text and (h)(2)(vi) are revised to read as follows:

### § 144.37 Withdrawal for exportation.

\* \* \* \* \*

(h) \* \* \*

(2) *Sales ticket content and handling.* Sales ticket withdrawals must be made only under a blanket permit to withdrawal (see § 19.6(d) of this

chapter) and the sales ticket will serve as the equivalent of the supplementary withdrawal. A sales ticket is an invoice of the proprietor's design which will include:

\* \* \* \* \*

(vi) A statement on the original copy (purchaser's copy) to the effect that goods purchased in a duty-free store will be subject to duty and/or tax with personal exemption if returned to the United States. At the time of purchase, the original sales ticket must be made out in the name of the purchaser and given to the purchaser. One copy of the sales ticket must be retained by the proprietor. This copy may be maintained electronically provided the port director is satisfied that the proprietor has the ability to print the sales ticket upon the request of a CBP officer. A permit file copy will be attached to the parcel containing the purchased articles unless the proprietor has established and maintained an effective method to match the parcel containing the purchased articles with the purchaser. Additional copies may be retained by the proprietor.

\* \* \* \* \*

**W. Ralph Basham,**

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

Approved: January 10, 2008.

**Timothy E. Skud,**

*Deputy Assistant Secretary of the Treasury.*

[FR Doc. E8-522 Filed 1-15-08; 8:45 am]

**BILLING CODE 9111-14-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Parts 314, 601, and 814

[Docket No. 2008N-0021]

### Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices

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

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to amend its regulations regarding changes to an approved new drug application (NDA), biologics license application (BLA), or medical device premarket approval application (PMA) to codify the agency's longstanding view on when a change to the labeling of an approved drug, biologic, or medical device may be made in advance of the agency's review

of such change. FDA is proposing to reaffirm its longstanding position that a supplemental application submitted under those provisions is appropriate to amend the labeling for an approved product only to reflect newly acquired information, as well as to clarify that such a supplemental application may be used to add or strengthen a contraindication, warning, precaution, or adverse reaction only if there is sufficient evidence of a causal association with the drug, biologic, or device. The amendments proposed by this document are intended to reflect the agency's existing practices with respect to supplemental applications submitted to FDA.

**DATES:** Submit written or electronic comments on the amendments proposed by this document by March 17, 2008. See section VIII of this document for the proposed effective date of any final rule that may publish based on this proposal.

**ADDRESSES:** You may submit comments, identified by Docket No. 2007M-0468 and/or RIN number \_\_ (if a RIN number has been assigned), by any of the following methods:

#### *Electronic Submissions*

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

- Agency Web site: <http://www.fda.gov/dockets/ecomments>. Follow the instructions for submitting comments on the agency Web site.

#### *Written Submissions*

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

**Instructions:** All submissions received must include the agency name and Docket No(s). and Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. All comments received may be posted without change to <http://www.fda.gov/ohrms/dockets/default.htm>, including any personal