

(nonsupervisory), XT (leader), and XU (supervisory).

(b) The Vicksburg District of the Mississippi Valley Division is comprised of the following four lakes:

- (1) Grenada Lake in Grenada County, MS
- (2) Enid Lake in Yalobusha County, MS
- (3) Sardis Lake in Panola County, MS
- (4) Arkabutla Lake in Tate County, MS

(c) Special wage schedules shall be established at the same time and with rates identical to the Memphis, TN, appropriated fund wage schedule.

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DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

DEPARTMENT OF THE TREASURY

19 CFR Parts 4, 7, 10, 12, 18, 19, 24, 54, 102, 113, 123, 125, 128, 132, 134, 141, 142, 143, 144, 145, 146, 148, 151, 152, 158, 163, 174, 181, and 191

[CBP Dec. No. 15-14; USCBP-2015-0045]

RIN 1515-AE03

Automated Commercial Environment (ACE) Filings for Electronic Entry/Entry Summary (Cargo Release and Related Entry)

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

ACTION: Interim final rule.

SUMMARY: This document amends the U.S. Customs and Border Protection (CBP) regulations to reflect that on November 1, 2015, the Automated Commercial Environment (ACE) will be a CBP-authorized Electronic Data Interchange (EDI) System. This regulatory document informs the public that the Automated Commercial System (ACS) is being phased out as a CBP-authorized EDI System for the processing electronic entry and entry summary filings (also known as entry filings). ACE will replace the Automated Commercial System (ACS) as the CBP-authorized EDI system for processing commercial trade data. This document also announces the conclusion of the ACE *Cargo Release* and the *Entry Summary, Accounts and Revenue* tests with regard to the entry and entry summary requirements that are now part of the CBP regulations.

DATES: *Effective Date:* This interim final rule is effective on November 1, 2015.

Written comments must be submitted on or before November 12, 2015.

ADDRESSES: You may submit comments, identified by docket number USCBP-2015-0045, by one of the following methods:

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

- *Mail:* Trade and Commercial Regulations Branch, Regulations and Rulings, Office of International Trade, U.S. Customs and Border Protection, 90 K Street NE., 10th Floor, Washington, DC 20229-1177.

Instructions: All submissions received must include the agency name and docket title for this rulemaking, and must reference docket number USCBP-2015-0045. 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 the 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 business days between the hours of 9:00 a.m. and 4:30 p.m. at the Office of International Trade, Customs and Border Protection, 90 K Street NE., 10th Floor, Washington, DC. Arrangements to inspect submitted comments should be made in advance by calling Mr. Joseph Clark at (202) 325-0118.

FOR FURTHER INFORMATION CONTACT: For policy questions related to ACE, contact Josephine Baiamonte, Director, Business Transformation, ACE Business Office, Office of International Trade, at josephine.baiamonte@cbp.dhs.gov. For technical questions, contact Steven Zaccaro, Client Representative Branch, ACE Business Office, Office of International Trade, at steven.j.zaccaro@cbp.dhs.gov. For legal questions, contact Robert Altneu, Chief, Trade and Commercial Regulations Branch, Regulations and Rulings, Office of International Trade, at robert.f.altneu@cbp.dhs.gov.

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. U.S. 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 to CBP in finalizing these regulations 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. See ADDRESSES above for information on how to submit comments.

I. Background

A. Statutory Authority

Section 484 of the Tariff Act of 1930, as amended (19 U.S.C. 1484), establishes the requirement for importers of record to make entry for merchandise to be imported into the customs territory of the United States. Customs entry information is used by CBP and partner government agencies to determine whether merchandise may be released from CBP custody.

The customs entry requirements were amended by Title VI of the North American Free Trade Agreement Implementation Act (Pub. L. 103-182, 107 Stat. 2057, December 8, 1993), commonly known as the Customs Modernization Act, or Mod Act. In particular, section 637 of the Mod Act amended section 484(a)(1)(A) of the Tariff Act (19 U.S.C. 1484(a)(1)(A)) by revising the requirement to make and complete customs entry by submitting documentation to CBP, to also allow in the alternative, the transmission of entry information electronically pursuant to a CBP-authorized electronic data interchange system. Further, section 634 of the Mod Act amended section 401 of the Tariff Act (19 U.S.C. 1401) to add definitions related to the electronic filing of the entry and entry summary. The term “electronic entry” is defined as the electronic transmission to CBP of entry information required for the entry of merchandise, and entry summary information required for the classification and appraisal of the merchandise, the verification of statistical information, and the determination of compliance with applicable law. The term “electronic transmission” is defined as the transfer of data or information through an authorized electronic data interchange system consisting of, but not limited to, computer modems and computer networks. The term “electronic data interchange system” is defined as any established mechanism approved by the CBP Commissioner through which information can be transferred electronically.

To implement the Mod Act, CBP has been modernizing the business processes essential to securing U.S. borders, facilitating the flow of legitimate shipments, and targeting illicit goods. The key automated system behind these initiatives is the Automated Commercial Environment (ACE). ACE is the backbone of CBP trade data processing and risk management activities and provides a single, centralized access point to connect CBP, other International Trade Data System (ITDS) agencies, and the trade community.

B. Executive Order 13659

On February 19, 2014, President Obama issued Executive Order (EO) 13659, *Streamlining the Export/Import Process for America's Businesses*, in order to reduce unnecessary procedural requirements to commerce while continuing to protect our national security, public health and safety, the environment, and natural resources. See 79 FR 10657 (February 25, 2014). Pursuant to EO 13659, participating Federal agencies shall have capabilities, agreements, and other requirements in place to utilize the International Trade Data System (ITDS) and supporting systems, such as the Automated Commercial Environment, as the primary means of receiving from users the standard set of data and other relevant documentation (exclusive of applications for permits, licenses, or certifications) required for the release of imported cargo and clearance of cargo for export no later than by December 31, 2016.

CBP will complete the development of core trade processing capabilities in ACE and decommission corresponding capabilities in legacy systems by the end of 2016. At that time, ACE will provide a Single Window for processing trade data, and become the primary system through which the international trade community will submit import and export data and the Government will determine admissibility.

C. Current Regulations

CBP established the specific requirements and procedures for the electronic filing of entry and entry summary data for imported merchandise through the Automated Broker Interface (ABI), originally a module of the Automated Commercial System (ACS), in a final rule (T.D. 90–92) published in the **Federal Register**. See 55 FR 49879 (December 3, 1990). The CBP regulations, in Subparts A and D of part 143 in Title 19 of the Code of Federal Regulations (CFR), allow for electronic filing of customs entry and

entry summary information through the ABI. ABI is defined as a module of the Automated Commercial System (ACS) that allows entry filers to transmit immediate delivery, entry, and entry summary data to CBP and to receive electronic messages. ACS is defined as CBP's integrated comprehensive tracking system for the acquisition, processing and distribution of import data. See 19 CFR 143.32.

D. Transitioning ABI From ACS to ACE

CBP has been developing and testing ACE over the last several years as the successor EDI system to ACS. CBP has provided significant public outreach through events and on-line information to help ensure that the international trade community is fully engaged in the transition from ACS to ACE as the system authorized by the Commissioner for processing entry and entry summary information. CBP has conducted numerous tests of the filing of entries and entry summaries through ACE. See Section E below.

During the transition from ACS to ACE, filers have continued to use the ABI functionality to transmit entry and entry summary information both to the ACS and ACE EDI systems. In this document, CBP is announcing, consistent with 19 U.S.C. 1401, that, with the conclusion of National Customs Automation Program (NCAP) tests discussed below, ACE will be an authorized electronic data interchange system authorized by the Commissioner to which entry and entry summary filings (also known as entry filings) can be transmitted electronically. It should be noted that Reconciliation entries are not affected by this change. See 63 FR 6257 (February 6, 1998). Reconciliation entries will continue to be filed under the procedures, terms and conditions governing Reconciliation.

E. National Customs Automation Program

As part of the transition from ACS to ACE, CBP has been conducting tests of ACE under the NCAP. The NCAP was established by Subtitle B of the Mod Act. See 19 U.S.C. 1411. The two tests relevant to the regulatory amendments included in this document are the *Cargo Release* test and the *Entry Summary, Accounts and Revenue*, or *ESAR*, test.

1. ACE Cargo Release Test

On November 9, 2011, CBP published a general notice in the **Federal Register** (76 FR 69755) announcing an NCAP test concerning *ACE Simplified Entry* to simplify the entry process by eliminating the submission of redundant data elements required to

obtain release for cargo imported by air. This test does not eliminate the submission of unique data elements. In a general notice titled "Modification of National Customs Automation Program Test Concerning Automated Commercial Environment (ACE) Cargo Release" published in the **Federal Register** (78 FR 66039) on November 4, 2013, CBP modified the *ACE Simplified Entry* test and renamed it the *ACE Cargo Release* test. The *Cargo Release* Test provided more capabilities to test participants and eliminated the requirement that test participants join the Customs-Trade Partnership Against Terrorism (C-TPAT) in order to increase participation. CBP modified the *Cargo Release* Test in a general notice published in the **Federal Register** (79 FR 6210) on February 3, 2014, to include the ocean and rail modes of transportation, and again in a general notice published in the **Federal Register** (80 FR 7487) on February 10, 2015, to change the name of one data element and allow authorized importers and licensed customs brokers to submit the *Cargo Release* entry and the Importer Security Filing (ISF) in a combined transmission to CBP. In addition, on March 27, 2015, CBP published a general notice in the **Federal Register** (80 FR 16414) to further modify the *Cargo Release* test to allow importers and customs brokers to file type 03 entries (*i.e.*, entries for merchandise subject to countervailing or antidumping duties) for all modes of transportation and to file, for cargo transported in the truck mode, entries for split shipments or partial shipments, and entry on cargo which has been moved in-bond from the first U.S. port of unloading.

2. Entry Summary, Accounts and Revenue (ESAR) Test

CBP has published several notices announcing ACE tests related to the *Entry Summary, Accounts and Revenue (ESAR)* capabilities. The first of these test notices (*ESAR I*), published by CBP in the **Federal Register** on October 18, 2007 (72 FR 59105), provided for enhanced account management functions for ACE Portal Accounts and expanded the universe of ACE account types. On August 26, 2008, CBP published a General Notice in the **Federal Register** (73 FR 50337) announcing the *ESAR II* test that concerned new Portal and EDI capabilities specific to entry summary filing and processing of consumption and informal entries. That notice stated that functionality will include ABI Census Warning Overrides and issuance of CBP requests for information and

notices of action through the ACE Portal, and that new functionality will enhance Portal Account Management and allow for ACE Secure Data Portal reporting. On March 6, 2009, CBP published the *ESAR III* test notice in the **Federal Register** (74 FR 9826) that announced the port-by-port phased deployment strategy for the *ESAR II* functionality. On June 24, 2011, CBP announced the *ESAR IV* test in the **Federal Register** (76 FR 37136). That test permitted importers to file post-summary corrections (PSCs) of certain ACE entry summaries using ABI.

F. Amendments to the CBP Regulations

The Cargo Release and ESAR Tests will terminate only with regard to requirements directly related to automated entry and entry summary that do not involve data from other ITDS agencies upon the effective date of this rule. Test participants may continue to participate in the test until that date.

As a result of the two tests discussed above having been successful, CBP is amending its regulations to provide that ACE is a CBP-authorized electronic data interchange (EDI) system for processing electronic entry and entry summary filings with CBP. As of the end of February 2016, CBP anticipates that ACE will be fully functional for filing entry and entry summary so that ACS will no longer be available for entry filings. CBP encourages filers to adjust their business practices by filing in ACE as of the effective date of this rule.

This rule amends sections 12.140, 24.23, 128.11, 128.23, 141.57, 141.58, 143.1, 143.31, 143.32, and 174.12 to replace references to the Automated Commercial System, or ACS, each place it appears in these sections with the phrase “ACE or any other CBP-authorized electronic data interchange system.” In section 24.23(a)(4)(i), regarding the Merchandise Processing Fee (MPF), we are retaining the reference to ACS, because that system will continue to be used to process payments, including MPF. We are adding the words “or any other CBP-authorized electronic data interchange system” to enable CBP to transition the payment processing functions to ACE at a later date.

This rule further amends certain definitions concerning the entry of merchandise in 19 CFR 141.0a to reflect that ACE is the CBP-authorized EDI system for processing trade data. In particular, the definitions for the following terms are revised to indicate filers may also submit required entry information electronically to ACE, as well as by paper, to CBP: “entry,” “entry summary,” “submission,”

“filing,” “entered for consumption,” “entered for warehouse,” and “entered temporarily under bond.” Similarly, this rule amends the definitions related to the special entry procedures in 19 CFR 143.32 to replace reference to ACS with reference to ACE. Specifically, this rule also revises in 19 CFR 143.32 the definitions of the terms “ABI,” “electronic immediate delivery,” and “statement processing,” and adds a definition of the term “authorized electronic data interchange system,” to indicate that ACS is will no longer be the only CBP-authorized EDI system.

As the Automated Broker Interface, or ABI, continues to be the functionality that allows entry filers to transmit immediate delivery, entry and entry summary data to CBP, and to receive transmissions from CBP, there is no need to amend references to that term. However, this rule amends 19 CFR 143.32 to correct the definition of ABI which currently defines ABI as a module of ACS. This definition is inaccurate because ABI is a functionality that operates separately from ACS.

This rule further amends the document filing procedures within 19 CFR parts 4, 7, 10, 12, 18–19, 24, 54, 102, 113, 123, 125, 128, 132, 134, 141–146, 148, 151–152, 158, 163, 174, 181, and 191 by providing filers with the option of transmitting electronic data to CBP. Specifically, this rule amends these parts to allow filers, in the alternative, to submit the electronic equivalent of CBP Forms (including CBP Forms 28, 29, 247, 434, 3229, 3289, 3299, 3311, 3461, 4315, 4455, 4457, 4647, 7501, 7533, and 7552) and other documents that may be required by CBP or other government agencies at the time of entry. These documents include the records and information required for the entry of merchandise listed in the Appendix to part 163 (commonly referred to as the “(a)(1)(A)” list). This amendment does not mean that an electronic equivalent exists, but merely that an electronic equivalent may be used when such an equivalent exists. Lastly, this rule makes technical corrections to the nomenclature of “Customs” or “Customs Service” to “CBP” in some existing regulatory text, and updates some text to comply with the Plain English initiative in regulatory drafting.

In consideration of the business process changes that may be necessary to achieve full compliance and to provide members of the trade community with sufficient time to transition from ACS to ACE, filers are encouraged to adjust their business practices at the current time so that they

can file in ACE before the end of February of 2016 when it is anticipated that ACS will no longer be supported for entry and entry summary. Filers who have technical questions should contact their assigned client representative. Filers without an assigned client representative should contact Steven Zaccaro, Client Representative Branch, ACE Business Office, Office of International Trade, at steven.j.zaccaro@cbp.dhs.gov. Additional information regarding the automation of the entry and entry summary processes is available on the following Web page: <http://www.cbp.gov/trade/automated>.

Filers interested in participating in these tests should review the notices published in the **Federal Register**. See e.g., *National Customs Automation Program (NCAP) Test Concerning the Submission of Certain Data Required by the Environmental Protection Agency and the Food Safety and Inspection Service Using the Partner Government Agency Message Set Through the Automated Commercial Environment (ACE)*, 78 FR 75931 (December 13, 2013); *Modification of National Customs Automation Program (NCAP) Test Concerning Automated Commercial Environment (ACE) Document Image System (DIS) Relating to Animal and Plant Health Inspection Service (APHIS) Document Submissions*, 80 FR 5126 (January 30, 2015); and *Modification of National Customs Automation Program (NCAP) Test Concerning the Use of Partner Government Agency Message Set through the Automated Commercial Environment (ACE) for the Submission of Certain Data Required by the Environmental Protection Agency (EPA)*, 80 FR 6098 (February 4, 2015). *Importation of Distilled Spirits, Wine, Beer, Tobacco Products, Processed Tobacco, and Cigarette Papers and Tubes; Availability of Pilot Program and Filing Instructions to Test the Collection of Import Data for Implementation of the International Trade Data System*, 80 FR 47558 (August 7, 2015).

G. Conclusion of Cargo Release and ESAR Tests

This document announces the conclusion of the *Cargo Release and Entry Summary, Accounts and Revenue* tests only with regard to the entry and entry summary requirements that are now part of the CBP regulations. All other aspects of the *Cargo Release and Entry Summary, Accounts and Revenue* tests remain on-going until ended by announcement in a subsequent **Federal Register** notice.

H. Proposal To Eliminate Hybrid Filing

Importers currently can file required forms electronically to a CBP-authorized electronic data interchange system, by paper, or a combination of both (hybrid filing). When importers file a paper or hybrid entry, they fill out the required documents on their computer, print the documents, and then send the documents to their broker or to the port of entry by either mail or a courier. CBP is considering proposing a rule to require importers to choose between submitting the required entry and entry summary documentation (including ITDS Agency documents) entirely electronically or entirely by paper. CBP would no longer accept any hybrid filings, except in limited circumstances. This would mean that if an importer files one paper document not covered by the limited exceptions, the entire filing, including the report to CBP, must be on paper.

While CBP is considering this proposal, comments are invited on all aspects of a policy to eliminate hybrid filings, including economic, operational, and feasibility of implementation. In particular, CBP is interested in data and views on the following:

1. Assessments of costs of implementing the proposal, including IT, training, and compliance. Comments should include a discussion about how the requirement to file all on paper or all in electronic form, if adopted, would affect business operations, cost to government of processing paper, and impact on health, safety, and the environment when enforcement and compliance agencies may see electronic data reduced.

2. Assessment of net benefits that may include processing enhancements, savings in processing time, and other perceived quantitative and qualitative benefits.

3. Estimates of time needed to comply with the proposal, if adopted.

4. Suggestions for including regulatory flexibilities such as phased-in compliance dates, exceptions, and safe harbors that will ease compliance for filers, especially those filers that are small entities.

5. Suggestions as to documentation and data that should be excepted from the proposed policy and supporting information to explain the appropriateness of the exception.

II. Statutory and Regulatory Requirements

A. Inapplicability of Notice

Pursuant to 5 U.S.C. 553(b)(3), public notice is inapplicable to these interim regulations because they concern

matters relating to agency procedure and practice inasmuch as the changes involve updates to the format of the electronic submission of data to CBP's proprietary electronic data interchange (EDI) system from ACS to ACE for persons filing required information related to the importation of merchandise pursuant to 19 U.S.C. 1401 and 1484. Further, good cause exists pursuant to 5 U.S.C. 553(d) and 808(2), to issue these regulations without a delay in effective date. The transition from ACS to ACE does not substantively alter the underlying rights or interests of importers or filers, only the manner in which they present required information to the agency. By shifting to a modified electronic format for the submission of required data, CBP will be able to more efficiently determine whether merchandise presented for importation is admissible into the United States. In addition, although this interim rule will be codified on November 1, 2015, CBP anticipates that filers can continue to file in ACS or ACE until February 2016, when ACE will be fully functional for filing entry and entry summary. Accordingly, CBP and Treasury have determined that the requirements for prior notice and a delay in effective date are inapplicable, however the agencies are soliciting comments in this interim rule and will consider all comments received before issuing a final rule.

B. Executive Orders 13563 and 12866

Executive Orders 13563 and 12866 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. OMB believes that this rule is an "economically significant regulatory action," under section 3(f) of Executive Order 12866.

When importing to the United States, importers may file the required entry and entry summary documents to CBP in two ways: By paper or electronically through the Automated Broker Interface (ABI). The technical requirements to file in ABI are spelled out in the CBP and Trade Automated Interface Requirements (the CATAIR), which is available to the public on CBP's Web

page.¹ The CATAIR is updated frequently due to changing technical specifications.

If the importer chooses to file electronically, it submits the required data in ABI and the data then gets transmitted from ABI to a CBP system for processing. Originally, ABI transmitted the data to only the Automated Commercial System (ACS). Currently, the data can be transmitted to either ACS or the Automated Commercial Environment (ACE), depending on whether the importer has met the relevant CATAIR requirements.

The existing regulations set forth the requirements for how filers interact with CBP through ABI. In doing so, the regulations make reference to ACS several times. This rule replaces the ACS references in the regulations with "ACE or any other CBP-authorized EDI system." This regulation also corrects the definition of ABI, which is currently defined as a module of ACS. This is an erroneous definition since ABI exists separately from ACS and is simply a functionality by which importers can file entries with CBP. With this rule, importers will continue to be able to file their entries electronically via ABI, which will now transmit all the entry data to ACE.

CBP acknowledges that importers and software developers who have not already made the changes required to transmit their entry information from ABI to ACE rather than to ACS will need to make these changes to comply with the ABI CATAIR specifications. The change in technical specifications for ABI filing is independent from this regulatory change. (Technical specifications change frequently and are done independently of any regulatory action.) What follows is a short analysis of the costs of the systems changes, some portion of which may be attributable to this rule.

Based on conversations with members of the trade community on CBP's Technical Advisory Group,² the costs of making the required systems changes to meet the CATAIR specifications to use ABI to transmit entries to ACE rather than to ACS are rather small. According to CBP's ACE Business Office, approximately 95 percent of importers who file entries electronically purchase software licenses from third-party software developers to more easily file entries in ABI. These software

¹ See <http://www.cbp.gov/trade/acs/catair> and <http://www.cbp.gov/trade/ace/catair>.

² The Technical Advisory Group advises CBP on ACE from the perspective of the Trade. It is made up of representatives of the trade community who are involved in the entry process, including importers, brokers, and software developers.

developers, and a small number of importers who file directly with CBP, would need to make programming changes to their software to make it compatible with ACE, if they have not already done so. Software developers charge an annual fee for the use of their software, which covers the cost of software updates, maintenance, and training. The developers do not anticipate raising rates as a result of making changes to ACE.

The cost of making software compatible with ACE will fall on the software developers and the 5 percent of importers who do not purchase a software product, because they develop their own software. CBP's ACE Business Office estimates that 150 businesses will need to make software modifications, including 112 importers who self-file and 38 software developers. According to the Technical Advisory Group, the cost of making these changes is covered by the existing fees software developers charge to their users. Many of these parties have already made the changes to take advantage of the added functionality available in ACE. According to CBP's ACE Business Office, of the 38 software developers that provide software to facilitate the filing of entries, 36 have already modified their systems to allow for filing in ACE. CBP does not know how many of the 112 self-filers have already modified their systems, but it is likely that many of these self-filers have already made the necessary changes. According to CBP data, as of April 2015, 53 percent of entries were filed in ABI in an ACE-compatible format. According to an estimate from a member of the Technical Advisory Group, it can cost from \$25,000 to \$90,000 to make the change to ACE formatting, including systems costs and training. This estimate also includes all the costs of converting to ACE, not just the cost of making the changes necessary to file entries in ACE format, so the actual costs necessary to file entries in ACE format is likely to be lower. Based on the range of costs to convert to ACE formatting, we estimate that it will cost our estimated 112 software vendors and 38 self-filers between \$3.75 million and \$13.5 million to file in ACE format. These estimates assume that all 150 software vendors and self-filers will incur costs to convert to ACE, which we previously noted is unlikely given that many of these parties have already made the change to take advantage of ACE's additional functionality. We invite comments on these estimates of system costs and on other transition costs.

This rule benefits the public by clarifying the information presented in

the regulations regarding how importers interact with CBP via ABI. The broader regulatory and non-regulatory shift from ACS to ACE has substantial benefits to federal agencies and the public. Transitioning to ACE will expedite cargo processing; improve compliance with CBP and other government agency regulations; provide greater efficiency in receiving, processing, and sharing import data which will increase the effectiveness of federal agencies; and reduce redundant information requirements for the importing community. We note that these benefits of the transition to ACE are characterized by the same analytic difficulty as the costs; it is not clear what portion is attributable to this rule as opposed to other regulatory and non-regulatory actions. We invite comments that would allow for reasonable attribution of effects across these various actions.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement and Fairness Act of 1996, requires an agency to prepare and make available to the public a regulatory flexibility analysis that describes the effect of a proposed rule on small entities (*i.e.*, small businesses, small organizations, and small governmental jurisdictions) when the agency is required to publish a general notice of proposed rulemaking for a rule. Since a general notice of proposed rulemaking is not necessary for this rule, CBP is not required to prepare a regulatory flexibility analysis for this rule.

D. Paperwork Reduction Act

As there is no collection of information proposed in this document, the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507) are inapplicable.

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 4

Customs duties and inspection, Entry, Exports, Freight, Harbors, Imports, Maritime carriers, Pollution, Reporting and recordkeeping requirements, Vessels.

19 CFR Part 7

American Samoa, Coffee, Customs duties and inspection, Guam, Guantanamo Bay, Imports, Insular possessions, Johnston Islands, Kingman Reef, Liquor, Midway Islands, Puerto Rico, Reporting and recordkeeping requirements, Wake Island, Wine.

19 CFR Part 10

Caribbean Basin initiative, Customs duties and inspection, Entry of merchandise, Exports, Imports, Reporting and recordkeeping requirements, Trade agreements.

19 CFR Part 12

Customs duties and inspection, Reporting and recordkeeping requirements.

19 CFR Part 18

Baggage, Bonds, Common carriers, Customs duties and inspection, Exports, Explosives, Foreign trade statistics, Freight, Imports, Merchandise in transit, Penalties, Prohibited merchandise, Railroad, Reporting and recordkeeping requirements, Restricted merchandise, Surety bonds, Transportation in bond, Vehicles, Vessels.

19 CFR Part 19

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

19 CFR Part 24

Accounting, Claims, Customs duties and inspection, Harbors, Imports, Reporting and recordkeeping requirements, Taxes.

19 CFR Part 54

Customs duties and inspection, Reporting and recordkeeping requirements.

19 CFR Part 102

Canada, Customs duties and inspection, Exports, Imports, Mexico, Reporting and recordkeeping requirements, Trade agreements.

19 CFR Part 113

Common carriers, Customs duties and inspection, Exports, Freight, Laboratories, Reporting and recordkeeping requirements, Surety bonds.

19 CFR Part 123

Administrative practice and procedure, Aircraft, Aliens, Baggage, Canada, Common carriers, Customs duties and inspection, Entry of merchandise, Fees, Forms (Written agreement), Freight, Immigration,

Imports, International boundaries (Land border), International traffic, Mexico, Motor carriers, Railroads, Repairs, Reporting and recordkeeping requirements, Test programs, Trade agreements, Treaties, Vehicles, Vessels.

19 CFR Part 125

Customs duties and inspection, Freight, Government contracts, Harbors, Reporting and recordkeeping requirements.

19 CFR Part 128

Administrative practice and procedure, Customs duties and inspection, Entry, Express consignments, Freight, Imports, Reporting and recordkeeping requirements.

19 CFR Part 132

Agriculture and agricultural products, Customs duties and inspection, Quotas, Reporting and recordkeeping requirements.

19 CFR Part 134

Canada, Country of origin, Customs duties and inspection, Imports, Labeling, Marking, Mexico, Packaging and containers, Reporting and recordkeeping requirements, Trade agreements.

19 CFR Part 141

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

19 CFR Part 142

Canada, Customs duties and inspection, Mexico, Reporting and recordkeeping requirements.

19 CFR Part 143

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

19 CFR Part 144

Customs duties and inspection, Reporting and recordkeeping requirements, Warehouses.

19 CFR Part 145

Customs duties and inspection, Exports, Lotteries, Reporting and recordkeeping requirements.

19 CFR Part 146

Administrative practice and procedure, Customs duties and inspection, Exports, Foreign trade zones, Imports, Penalties, Petroleum, Reporting and recordkeeping requirements.

19 CFR Part 148

Airmen, Aliens, Baggage, Crewmembers, Customs duties and inspection, Declarations, Foreign officials, Government employees, International organizations, Privileges and immunities, Reporting and recordkeeping requirements, Seamen, Taxes, Trade agreements (U.S.-Canada Free-Trade Agreement).

19 CFR Part 151

Cigars and cigarettes, Cotton, Customs duties and inspection, Fruit juices, Laboratories, Metals, Imports, Reporting and recordkeeping requirements, Sugar, Wool.

19 CFR Part 152

Appraisal, Classification, Customs duties and inspection, Valuation.

19 CFR Part 158

Computer technology, Customs duties and inspection, Exports, Freight, Merchandise (lost, damaged, abandoned, exported), Reporting and recordkeeping requirements.

19 CFR Part 163

Administrative practice and procedure, Customs duties and inspection, Exports, Imports, Penalties, Reporting and recordkeeping requirements.

19 CFR Part 174

Administrative practice and procedure, Customs duties and

inspection, Protests, Reporting and recordkeeping requirements, Trade agreements.

19 CFR Part 181

Administrative practice and procedure, Canada, Customs duties and inspection, Exports, Imports, Mexico, Reporting and recordkeeping requirements, Trade agreements.

19 CFR Part 191

Alcohol and alcoholic beverages, Claims, Customs duties and inspection, Exports, Foreign trade zones, Guantanamo Bay Naval Station, Cuba, Packaging and containers, Reporting and recordkeeping requirements, Trade agreements.

Amendments to the CBP Regulations

For the reasons stated above in the preamble, CBP amends parts 4, 7, 10, 12, 18, 19, 24, 54, 102, 113, 123, 125, 128, 132, 134, 141, 142, 143, 144, 145, 146, 148, 151, 152, 158, 163, 174, 181, and 191 of title 19 of the Code of Federal Regulations (19 CFR parts 4, 7, 10, 12, 18, 19, 24, 54, 102, 113, 123, 125, 128, 132, 134, 141, 142, 143, 144, 145, 146, 148, 151, 152, 158, 163, 174, 181, and 191) to read as follows:

PART 4—VESSELS IN FOREIGN AND DOMESTIC TRADES

■ 1. The general authority citation for Part 4 continues to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1431, 1433, 1434, 1624, 2071 note; 46 U.S.C. 501, 60105.

* * * * *

■ 2. In the table below, for each section indicated in the left column, after the words indicated in the middle column, wherever they appear in the section, add the words indicated in the right column:

Section	Words	Add
4.41(a)	Form 7501,	or its electronic equivalent,
4.94a	Form 7501	, or its electronic equivalent

PART 7—CUSTOMS RELATIONS WITH INSULAR POSSESSIONS AND GUANTANAMO BAY NAVAL STATION

■ 3. The authority citation for Part 7 continues to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States), 1623, 1624; 48 U.S.C. 1406i.

■ 4. In the table below, for each section indicated in the left column, after the

words indicated in the middle column, wherever they appear in the section, add the words indicated in the right column:

Section	Words	Add
7.3(f)	Form 3229	, or its electronic equivalent,

PART 10—ARTICLES CONDITIONALLY FREE, SUBJECT TO A REDUCED RATE, ETC.

Authority: 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States (HTSUS)), 1321, 1481, 1484, 1498, 1508, 1623, 1624, 3314.

■ 6. In the table below, for each section indicated in the left column, after the words indicated in the middle column, wherever they appear in the section, add the words indicated in the right column:

■ 5. The general authority citation for Part 10 continues to read as follows:

* * * * *

Section	Words	Add
10.1(g)(1)	Form 3311	, or its electronic equivalent,
10.1(g)(2) introductory text	Form 3311	, or its electronic equivalent,
10.1(g)(3)	Form 3311	, or its electronic equivalent,
10.1(h)(1) introductory text	Form 3311	, or its electronic equivalent,
10.1(h)(2)	Form 3311	, or its electronic equivalent,
10.1(h)(3) introductory text	Form 3311	, or its electronic equivalent,
10.1(h)(5)	Form 3311	, or its electronic equivalent,
10.1(i)	Form 3311	, or its electronic equivalent,
10.1(j)(2)	Form 7501	, or its electronic equivalent,
10.1(j)(2)	Form 3311	, or its electronic equivalent,
10.5(d)	Form 4455	, or its electronic equivalent
10.5(e)	CF 4455	, or its electronic equivalent
10.5(f)	Form 4455	, or its electronic equivalent
10.5(g)	Form 4455	, or its electronic equivalent
10.6	Form 4455	, or its electronic equivalent,
10.31(a)(1)	Form 3461 or 7501	, or their electronic equivalents
10.31(a)(2)	Form 7501	, or its electronic equivalent,
10.31(a)(2)	Form 3461	, or its electronic equivalent,
10.48(b)	A declaration	, or its electronic equivalent,
10.49(a)	a declaration	, or its electronic equivalent,
10.53(a)	face of the entry	, or its electronic equivalent,
10.53(e)(5)	USFWS Form 3–177	, or its electronic equivalent
10.59(e)	Form 7501	, or its electronic equivalent,
10.60(a)	Form 7501	, or its electronic equivalent.
10.60(d)	Form 7501	, or its electronic equivalent,
10.61	Form 7501	, or its electronic equivalent,
10.62(a) introductory text	Form 7501	, or its electronic equivalent,
10.62(b)	Form 7501	, or its electronic equivalent,
10.62(c)(2)	Form 7501	, or its electronic equivalent,
10.62a(a)	Form 7501	, or its electronic equivalent,
10.62a(b)	Form 7501	, or its electronic equivalent
10.66(a)(1)	Form 3311	, or its electronic equivalent
10.66(a)(2)	Form 4455	, or its electronic equivalent,
10.66(c)(1) introductory text	Form 4455	, or its electronic equivalent,
10.66(c)(2)	Form 4455	, or its electronic equivalent,
10.67(a)(1)	Form 3311	, or its electronic equivalent
10.67(a)(2)	A declaration	, or its electronic equivalent,
10.67(a)(3)	A declaration of the ultimate consignee	, or its electronic equivalent,
10.67(c)	Form 4455	, or its electronic equivalent,
10.68(a)	Form 3299	, or its electronic equivalent
10.68(a)	Form 4455	, or its electronic equivalent,
10.68(c)	Form 4455	, or its electronic equivalent,
10.69	Descriptive lists	, or their electronic equivalents,
10.70(a)	Department of Agriculture a certificate	, or its electronic equivalent,
10.70(a)	certificates of pedigree and transfer of ownership	, or their electronic equivalents,
10.70(a)	such certificates and transfers	, or their electronic equivalents
10.71(a)	a certificate of pure breeding	, or its electronic equivalent,
10.80	Form 7501	, or its electronic equivalent.
10.81(b)	Form 7501	, or its electronic equivalent,
10.84(b)(1)	a certificate	, or its electronic equivalent,
10.84(b)(2)	a certificate	, or its electronic equivalent,
10.84(b)(3)	a certificate	, or its electronic equivalent,
10.84(b)(4)	of this section	, or their electronic equivalents,
10.84(b)(6)(i)	bill of lading	, or the electronic equivalent,
10.84(b)(6)(ii)	The certificate	, or its electronic equivalent,
10.90(b)	The invoice	, or its electronic equivalent,
10.90(b)	statement of the cost of production	, or its electronic equivalent
10.98(c)	a declaration of the importer	, or its electronic equivalent,
10.99(a)	a declaration	, or its electronic equivalent,
10.101(b)	Form 3461	, or its electronic equivalent,

Section	Words	Add
10.102(a)	or bill	, or their electronic equivalents,
10.102(a)	pro forma invoice	, or its electronic equivalent,
10.102(b)	The certificates may be	submitted electronically,
10.102(b)	Form 7501	, or its electronic equivalent
10.104	Form 7501	, or its electronic equivalent
10.107(a)(1)	a report	, or its electronic equivalent,
10.121(a)	U.S. Department of State	, or its electronic equivalent,
10.179(a)	certificate from the importer	, or its electronic equivalent,
10.180(a)	meat-inspection certificate	, or its electronic equivalent,

PART 12—SPECIAL CLASSES OF MERCHANDISE

■ 7. The general authority citation for Part 12 and the sectional authority citation for § 12.140 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 (HTSUS)), 1624.

* * * * *
 Section 12.140 also issued under 19 U.S.C. 1484, 2416(a), 2171;
 * * * * *

■ 8. In the table below, for each section indicated in the left column, after the words indicated in the middle column, wherever they appear in the section, add the words indicated in the right column:

Section	Words	Add
12.6(a)(1)	An affidavit	, or its electronic equivalent
12.6(a)(2)	An affidavit	, or its electronic equivalent
12.7(a)	a valid permit	, or its electronic equivalent,
12.11(a)	a notice of arrival	, or its electronic equivalent,
12.11(a)	form	, or its electronic equivalent,
12.11(a)	the notice of arrival	, or its electronic equivalent,
12.34(b)	country of manufacture	, or its electronic equivalent,
12.34(e)	declaration	, or its electronic equivalent,
12.41(a)	Form 3311	, or its electronic equivalent,
12.43(a)	certificate of origin	, or its electronic equivalent,
12.43(a)	an additional certificate	, or its electronic equivalent,
12.43(b)	a statement	, or its electronic equivalent,
12.43(c)	of this section	, or their electronic equivalents,
12.80(e)(2)	Form 4647	, or its electronic equivalent
12.85(c)(1)	declaration	, or its electronic equivalent,
12.85(c)(2)	Declaration	, or its electronic equivalent,
12.85(c)(2)	A copy of the exemption	, or its electronic equivalent
12.85(c)(3)	declaration	, or its electronic equivalent,
12.85(c)(4)	declaration	, or its electronic equivalent,
12.85(c)(5)	declaration	, or its electronic equivalent,
12.85(c)(6)	declaration	, or its electronic equivalent,
12.85(d)(1)	Form CG-5096	, or its electronic equivalent
12.91(d)	Form 4647	, or its electronic equivalent
12.99(a) introductory text	a declaration	, or its electronic equivalent
12.99(b)	the declaration	, or its electronic equivalent,
12.99(b)	copy of the contract	, or its electronic equivalent,
12.104c(a)	A certificate	, its electronic equivalent
12.104c(a)	or permit	, or their electronic equivalents,
12.104c(d)(1)(i) introductory text	declarations under oath	, or their electronic equivalents,
12.104c(d)(1)(ii)	A statement	, or its electronic equivalent,
12.104c(d)(2)(i)	declarations under oath	, or their electronic equivalents,
12.104c(d)(2)(ii)	A statement	, or its electronic equivalent,
12.104d	or evidence	, or the electronic equivalent,
12.104e(a) introductory text	or evidence	, or the electronic equivalent,
12.107(a)	A certificate	, or its electronic equivalent
12.140(b) introductory text	Form 7501	, or its electronic equivalent
12.140(b)(2)(ii)	Form 7501	, or its electronic equivalent
12.142(c)(1) introductory text	Form 7501	, or its electronic equivalent

§ 12.140 [Amended]

■ 9. Amend § 12.140, in paragraph (b)(1) by removing the words “Automated Commercial System” and adding in their place the words “Automated Commercial Environment (ACE) or any other CBP-authorized electronic data interchange system”.

PART 18—TRANSPORTATION IN BOND AND MERCHANDISE IN TRANSIT

■ 10. The general authority citation for Part 18 continues 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), 1551, 1552, 1553, 1623, 1624.

* * * * *

■ 11. In the table below, for each section indicated in the left column, after the words indicated in the middle column, wherever they appear in the section, add the words indicated in the right column:

18.6(b)	Form 4647	, or its electronic equivalent
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PART 19—CUSTOMS WAREHOUSES, CONTAINER STATIONS AND CONTROL OF MERCHANDISE THEREIN

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

words indicated in the middle column, wherever they appear in the section, add the words indicated in the right column:

■ 12. The general authority citation for Part 19 continues to read as follows:

■ 13. In the table below, for each section indicated in the left column, after the

19.6(d)(2)	Form 7501	, or its electronic equivalent,
19.6(d)(5)	Form 7501	, or its electronic equivalent
19.9(c)	7501	, or its electronic equivalent
19.9(c)	Form 3461	, or its electronic equivalent,
19.11(b)	Form 7501	, or its electronic equivalent,
19.11(g)	Form 7501	, or its electronic equivalent,
19.14(a)	Form 7501	, or its electronic equivalent,
19.15(b)	Form 7501	, or its electronic equivalent,
19.15(d)	Form 7501	, or its electronic equivalent,

PART 24—CUSTOMS FINANCIAL AND ACCOUNTING PROCEDURE

Tariff Schedule of the United States), 1505, 1520, 1624; 26 U.S.C. 4461, 4462; 31 U.S.C. 3717, 9701; Public Law 107–296, 116 Stat. 2135 (6 U.S.C. 1 *et seq.*).
* * * * *

■ 15. In the table below, for each section indicated in the left column, after the words indicated in the middle column, wherever they appear in the section, add the words indicated in the right column:

■ 14. The general authority citation for Part 24 and the sectional authority for § 24.23 continue to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 58a–58c, 66, 1202 (General Note 3(i), Harmonized

Section 24.23 also issued under 19 U.S.C. 3332;
* * * * *

24.5(d)	Form 7501	, or its electronic equivalent,
24.5(e)	Form 7501	, or its electronic equivalent,
24.24(e)(2)(ii)	Form 7501	, or its electronic equivalent

§ 24.23 [Amended]

■ 16. Amend § 24.23, in paragraph (a)(4)(i) by adding after the words “Automated Commercial System (ACS)” the words “or any other CBP-authorized electronic data interchange system”.

PART 54—CERTAIN IMPORTATIONS TEMPORARILY FREE OF DUTY

■ 17. The authority citation for part 54 continues to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 3(i); Section XV, Note 5, Harmonized

Tariff Schedule of the United States), 1623, 1624.

■ 18. In the table below, for each section indicated in the left column, after the words indicated in the middle column, wherever they appear in the section, add the words indicated in the right column:

54.5(b)	declaration of the importer	, or its electronic equivalent,
54.6(a)	statement of the importer	, or its electronic equivalent,
54.6(b)	Form 7501	, or its electronic equivalent

PART 102—RULES OF ORIGIN

■ 19. The authority citation for part 102 continues to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States), 1624, 3314, 3592.

■ 20. In the table below, for each section indicated in the left column, after the

words indicated in the middle column, wherever they appear in the section, add the words indicated in the right column:

102.23(a)	Form 7501	, or its electronic equivalent,
102.23(a)	Form 3461	, or its electronic equivalent,
102.25	Certificate of Eligibility	, or its electronic equivalent,
Appendix to Part 102	Form 7501	, or its electronic equivalent,
Appendix to Part 102	Form 3461	, or its electronic equivalent,

PART 113—CUSTOMS BONDS

■ 21. The general authority citation for part 113 continues to read as follows:

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

■ 22. In the table below, for each section indicated in the left column, after the

words indicated in the middle column, wherever they appear in the section, add the words indicated in the right column:

113.41	Form 7501	, or its electronic equivalent,
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PART 123—CBP RELATIONS WITH CANADA AND MEXICO

Authority: 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States), 1431, 1433, 1436, 1448, 1624, 2071 note.
* * * * *

■ 24. In the table below, for each section indicated in the left column, after the words indicated in the middle column, wherever they appear in the section, add the words indicated in the right column:

■ 23. The general authority citation for part 123 continues to read as follows:

123.4(b)	Form 7501	, or its electronic equivalent,
123.4(c)	Form 3311	, or its electronic equivalent,
123.92(b)(2)(iii)	Form 3311	, or its electronic equivalent

PART 125—CARTAGE AND LITERAGE OF MERCHANDISE

Authority: 19 U.S.C. 66, 1565, and 1624.
* * * * *

words indicated in the middle column, wherever they appear in the section, add the words indicated in the right column:

■ 25. The general authority citation for part 125 continues to read as follows:

■ 26. In the table below, for each section indicated in the left column, after the

125.31(b)	Form 7501	, or its electronic equivalent
125.32	Form 7501	, or its electronic equivalent

PART 128—EXPRESS CONSIGNMENTS

Authority: 19 U.S.C. 58c, 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States), 1321, 1484, 1498, 1551, 1555, 1556, 1565, 1624.

words indicated in the middle column, wherever they appear in the section, add the words indicated in the right column:

■ 27. The authority citation for part 128 continues to read as follows:

■ 28. In the table below, for each section indicated in the left column, after the

128.24(b)	Form 3461	, or its electronic equivalent
128.24(c)	Form 3461	, or its electronic equivalent,
128.24(d)	Form 7501	, or its electronic equivalent

§ 128.11 [Amended]

■ 29. Amend § 128.11, in paragraph (b)(7)(i) by removing the words “Customs Automated Commercial System (ACS) and associated modules,” and adding in their place the words “CBP Automated Commercial Environment (ACE) or any other CBP-authorized electronic data interchange system, and associated applications.”

■ 30. Amend § 128.23 by revising paragraph (b) to read as follows:

§ 128.23 Entry requirements.

* * * * *

(b) *Procedures*—(1) *General*. All express consignment entities utilizing the procedures in this part must comply

with the requirements of the CBP Automated Commercial Environment (ACE) or any other CBP-authorized electronic data interchange system. These requirements include those under the Automated Manifest System (AMS), Cargo Selectivity, Statement Processing, the Automated Broker Interface System (ABI), and enhancements of ACE or any other CBP-authorized electronic data interchange system.

(2) *Entry number*. All entry numbers must be furnished to CBP in a CBP approved bar coded readable format in order to assist in the processing of express consignment cargo under the CBP Automated Commercial Environment (ACE) or any other CBP-

authorized electronic data interchange system.

* * * * *

PART 132—QUOTAS

■ 31. The general authority citation for part 132 continues to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States (HTSUS)), 1623, 1624.

* * * * *

■ 32. In the table below, for each section indicated in the left column, after the words indicated in the middle column, wherever they appear in the section, add the words indicated in the right column:

132.11a(a)(1)	entry summary for consumption,	or its electronic equivalent,
132.11a(a)(2)	entry summary for consumption,	or its electronic equivalent,
132.11a(a)(3)	entry summary for consumption,	or its electronic equivalent,
132.13(a)(1)(i)	entry summary for consumption,	or its electronic equivalent,
132.13(a)(1)(ii)	entry summary for consumption,	or its electronic equivalent,
132.13(a)(1)(iii) introductory text	the initial presentation of the entry summaries for consumption or withdrawals for consumption	or their electronic equivalents,
132.13(a)(1)(iii)(A)	or withdrawals for consumption,	or their electronic equivalents,
132.13(a)(2)	or withdrawal for consumption,	, or their electronic equivalents,

PART 134—COUNTRY OF ORIGIN MARKING

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States (HTSUS)), 1304, 1624.

words indicated in the middle column, wherever they appear in the section, add the words indicated in the right column:

■ 33. The authority citation for part 134 continues to read as follows:

■ 34. In the table below, for each section indicated in the left column, after the

134.51(a)	Form 4647	, or its electronic equivalent,
134.52(a)	Form 4647	, or its electronic equivalent,

PART 141—ENTRY OF MERCHANDISE

Authority: 19 U.S.C. 66, 1448, 1484, 1498, 1624.

■ 36. In the table below, for each section indicated in the left column, after the words indicated in the middle column, wherever they appear in the section, add the words indicated in the right column:

■ 35. The general authority citation for part 141 and the sectional authority for § 141.66 continue to read as follows:

* * * * *
Section 141.66 also issued under 19 U.S.C. 1490, 1623.
* * * * *

141.57(d)(2)	CF 3461/CF 3461 ALT,	or its electronic equivalent,
141.61(b)	Form 7501	, or its electronic equivalent
141.61(d) introductory text	Form 7501	, or its electronic equivalent,
141.61(d)(1)	7501 (boxes 10 and 12)	, or its electronic equivalent,
141.61(d)(1)	(box 12)	, or its electronic equivalent,
141.61(d)(1)	(box 10)	, or its electronic equivalent
141.61(d)(2)	(box12)	, or its electronic equivalent,
141.61(d)(2)	(box 10)	, or its electronic equivalent
141.61(d)(3)	(box 22)	, or its electronic equivalent
141.61(d)(4)	Form 7501	, or its electronic equivalent
141.61(e)(1)(i)(A)	Form 7501	, or its electronic equivalent
141.61(e)(1)(ii)(B)	Form 7501	, or its electronic equivalent
141.61(e)(1)(ii)(C)	Form 7501	, or its electronic equivalent,
141.61(f)(1)(iv)	Form 7501	, or its electronic equivalent,
141.61(f)(2)(i)	Form 7501	, or its electronic equivalent
141.68(g)(1)	Form 7501	, or its electronic equivalent,
141.68(g)(2)	Form 7501	, or its electronic equivalent
141.68(h)	Form 7501	, or its electronic equivalent
141.68(h)	or 7501	, or its electronic equivalent,
141.113(g)	Form 4647	, or its electronic equivalent,

■ 37. Revise § 141.0a to read as follows:

§ 141.0a Definitions.

Unless the context requires otherwise or a different definition is prescribed, the following terms will have the meanings indicated when used in connection with the entry of merchandise:

(a) *Entry*. “Entry” means that documentation or data required by § 142.3 of this chapter to be filed with the appropriate CBP officer or submitted electronically to the Automated Commercial Environment (ACE) or any other CBP-authorized electronic data interchange system to secure the release of imported merchandise from CBP custody, or the act of filing that documentation. “Entry” also means that documentation or data required by § 181.53 of this chapter to be filed with CBP to withdraw merchandise from a duty-deferral program in the United States for exportation to Canada or Mexico or for entry into a duty-deferral program in Canada or Mexico.

(b) *Entry summary*. “Entry summary” means any other documentation or electronic submission of data necessary

to enable CBP to assess duties, and collect statistics on imported merchandise, and determine whether other requirements of law or regulation are met.

(c) *Submission*. “Submission” means the voluntary delivery to the appropriate CBP officer or electronic submission to the Automated Commercial Environment (ACE) or any other CBP-authorized electronic data interchange system of the entry summary documentation or data for preliminary review or of entry documentation or data for other purposes.

(d) *Filing*. “Filing” means:

(1) The delivery to CBP, including electronic submission to the Automated Commercial Environment (ACE) or any other CBP-authorized electronic data interchange system, of the entry documentation or data required by section 484(a), Tariff Act of 1930, as amended (19 U.S.C. 1484(a)), to obtain the release of merchandise, or

(2) The delivery to CBP, including electronic submission to the Automated Commercial Environment (ACE) or any other CBP-authorized electronic data

interchange system, together with the deposit of estimated duties, of the entry summary documentation or data required to assess duties, collect statistics, and determine whether other requirements of law and regulation are met, or

(3) The delivery to CBP, including electronic submission to the Automated Commercial Environment (ACE) or any other CBP-authorized electronic data interchange system, together with the deposit of estimated duties, of the entry summary documentation or data, which will serve as both the entry and the entry summary.

(e) *Presentation*. “Presentation” is used only in connection with quota-class merchandise and is defined in § 132.1(d) of this chapter.

(f) *Entered for consumption*. “Entered for consumption” means that an entry summary for consumption has been filed with CBP in proper form, including electronic submission to the Automated Commercial Environment (ACE) or any other CBP-authorized electronic data interchange system, with estimated duties attached. “Entered for consumption” also means the necessary

documentation has been filed with CBP to withdraw merchandise from a duty-deferral program in the United States for exportation to Canada or Mexico or for entry into a duty-deferral program in Canada or Mexico (see § 181.53 of this chapter).

(g) *Entered for warehouse.* “Entered for warehouse” means that an entry summary for warehouse has been filed with CBP in proper form, including electronic submission to the Automated Commercial Environment (ACE) or any other CBP-authorized electronic data interchange system.

(h) *Entered temporarily under bond.* “Entered temporarily under bond” means that an entry summary supporting a temporary importation under bond has been filed with CBP in proper form, including electronic submission to the Automated Commercial Environment (ACE) or any

other CBP-authorized electronic data interchange system.

(i) *Released conditionally.* “Released conditionally” means any release from CBP custody before liquidation.

§ 141.57 [Amended]

■ 38. Amend § 141.57, in paragraph (d)(2) by removing the words “through the Customs Automated Commercial System (ACS)” and replacing them with the words “to the CBP Automated Commercial Environment (ACE) or any other CBP-authorized electronic data interchange system”.

§ 141.58 [Amended]

■ 39. Amend § 141.58, in paragraph (e) by removing the words “through the Customs Automated Commercial System (ACS)” and adding in their place the words “to the CBP Automated Commercial Environment (ACE) or any

other CBP-authorized electronic data interchange system”.

§ 141.66 [Amended]

■ 40. Amend § 141.66 by removing the word “documents” and adding in its place the word “documentation” in the heading; and removing the word “document” and adding in its place the word “documentation” in the regulatory text.

PART 142—ENTRY PROCESS

■ 41. The authority citation for part 142 continues to read as follows:

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

■ 42. In the table below, for each section indicated in the left column, after the words indicated in the middle column, wherever they appear in the section, add the words indicated in the right column:

142.3(a)(1)	Form 3461 (appropriately modified)	, or its electronic equivalent,
142.3(a)(1)	Form 7533 (appropriately modified)	, or its electronic equivalent,
142.3(a)(6)	Form 3461, 3461 ALT, 7501	, or their electronic equivalents.
142.3(b)(1)	Form 3461 or 7533	, or their electronic equivalents,
142.3(b)(2)	7501 or CBP Form 3311	, or their electronic equivalent
142.22(a)	Form 3461	, or its electronic equivalent
142.24(a)	Form 3461	, or its electronic equivalent
142.47(b)	CF 3461 or 3461 Alternate	, or its electronic equivalent,

■ 43. Section 142.11 is revised to read as follows:

§ 142.11 Entry summary form.

(a) *CBP Form 7501.* The entry summary must be on the CBP Form 7501, or its electronic equivalent, unless a different form or format is prescribed elsewhere in this chapter. CBP Form 7501, or its electronic equivalent, must be used for merchandise formally entered for consumption, formally entered for warehouse, or rewarehouse in accordance with § 144.11 of this chapter, and formally entered temporarily under bond under § 10.31 of this chapter. The entry summary for merchandise which may be entered free of duty in accordance with § 10.1(g) or (h) may be on CBP Form 3311, or its electronic equivalent, instead of on a CBP Form 7501 (or its electronic equivalent). For merchandise entitled to be entered under an informal entry, see § 143.23 of this chapter.

(b) *Extra copies.* The port director may require additional copies of the entry summary if filed in paper.

■ 44. Section 142.16 is revised to read as follows:

§ 142.16 Entry summary documentation.

(a) *Entry summary not filed at time of entry.* When the entry documentation is filed in paper before the entry summary documentation, one copy of the entry document and the commercial invoice, or the documentation filed in place of a commercial invoice in the instances listed in § 141.83(d) of this chapter, will be returned to the importer after CBP authorizes release of the merchandise. Entry documentation may also be transmitted electronically to the CBP Automated Commercial Environment (ACE) or any other CBP-authorized electronic data interchange system. The importer may use these documents in preparing the entry summary, CBP Form 7501, or its electronic equivalent, and must file them with the entry summary documentation within the time period stated in § 142.12(b). The entry summary documentation also must include any other documentation required for a particular shipment

unless a bond for missing documentation is on file, as provided in § 141.66 of this chapter.

(b) *Entry summary filed at time of entry.* When the entry summary documentation is filed or transmitted electronically at time of entry, the documentation listed in § 142.3 must be filed at the same time, except that CBP Form 3461 or 7533, or their electronic equivalents, will not be required. The importer also must file any additional invoice required for a particular shipment.

PART 143—SPECIAL ENTRY PROCEDURES

■ 45. The authority citation for part 143 continues to read as follows:

Authority: 19 U.S.C. 66, 1321, 1414, 1481, 1484, 1498, 1624, 1641.

■ 46. In the table below, for each section indicated in the left column, after the words indicated in the middle column, wherever they appear in the section, add the words indicated in the right column:

143.12	Form 7501	, or its electronic equivalent
143.13(a)	statements of cost	, or their electronic equivalents,
143.13(b)	A declaration	, or its electronic equivalent,
143.23 introductory text	Form 7501	, or its electronic equivalent
143.23(b)	Form 3311	, or its electronic equivalent,

143.23(c)	Form 3299	, or its electronic equivalent,
143.23(f)	Form 7501	, or its electronic equivalent
143.23(h)(1)	Form 3311	, or its electronic equivalent,
143.23(h)(2)	Form 3311	, or its electronic equivalent,
143.23(h)(2)	Form 7501	, or its electronic equivalent
143.24	Form 7501	, or its electronic equivalent,
143.25 heading	entry form	, or its electronic equivalent
143.25	Form 7501	, or its electronic equivalent,
143.32(g)	Forms 7501, 3461	, or their electronic equivalents
143.32(h)	Forms 7501 and 3461	, or their electronic equivalents

■ 47. Section § 143.1 introductory text is revised to read as follows:

§ 143.1 Eligibility.

The Automated Broker Interface (ABI) allows participants to transmit data electronically to CBP through ABI and to receive transmissions from Automated Commercial Environment (ACE) or any other CBP-authorized electronic data interchange system. Its purposes are to improve administrative efficiency, enhance enforcement of customs and related laws, lower costs and expedite the release of cargo.

* * * * *

§ 143.31 [Amended]

■ 48. Amend § 143.31, in first sentence, by removing the words “Customs Automated Commercial System (ACS)” and adding in their place the words “CBP Automated Commercial Environment (ACE) or any other CBP-authorized electronic data interchange system”.

■ 49. Section 143.32 is amended by revising paragraphs (a), (b), (j) and (p) to read as follows:

§ 143.32 Definitions.

* * * * *

(a) *ABI*. “ABI” means the Automated Broker Interface functionality that allows entry filers to transmit immediate delivery, entry and entry summary data electronically to, and receive electronic messaging from, CBP and receive transmissions from Automated Commercial Environment (ACE) or any other CBP-authorized electronic data interchange system.

(b) *Authorized electronic data interchange system* means any established mechanism approved by the Commissioner of CBP through which information can be transferred electronically.

* * * * *

(j) *Electronic immediate delivery*. “Electronic immediate delivery” means the electronic transmission of CBP Forms 3461 or 3461 alternate (CBP Form 3461 ALT) data to the Automated Commercial Environment (ACE) or any other CBP-authorized electronic data interchange system in order to obtain the release of goods under immediate delivery.

* * * * *

(p) *Statement processing*. “Statement processing” means the method of collection and accounting which allows a filer to pay for more than one entry summary with one payment. ACS, or

any other CBP-authorized electronic data interchange system, generates the statement, which is transmitted electronically to the filer, consisting of a list of entry summaries and the amount of duties, taxes or fees, if any, due for payment. Upon payment and collection of the statement, those entry summaries designated as electronic will be scheduled for liquidation (see § 24.25 of this chapter).

* * * * *

§ 143.33 [Amended]

■ 50. Amend § 143.33 by removing the words “of ACS”.

PART 144—WAREHOUSE AND RE-WAREHOUSE ENTRIES AND WITHDRAWALS

■ 51. The general authority citation for Part 144 continues to read as follows:

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

* * * * *

■ 52. In the table below, for each section indicated in the left column, after the words indicated in the middle column, wherever they appear in the section, add the words indicated in the right column:

144.11(a)	Form 7501	, or its electronic equivalent
144.11(a)	Form 3461 or 7533	, or their electronic equivalents,
144.11(b) heading and (b)	Form 7501	, or its electronic equivalent
144.11(c)	Form 7501	, or its electronic equivalent
144.12	Form 7501	, or its electronic equivalent
144.14 introductory text	Form 7501	, or its electronic equivalent
144.22(a) introductory text	Form 7501	, or its electronic equivalent,
144.36(b)	Form 7501	, or its electronic equivalent,
144.37(a)	7501	, or its electronic equivalent,
144.38(a)	Form 7501	, or its electronic equivalent
144.38(e)	Form 7501	, or its electronic equivalent,
144.41(b)	Form 7501	, or its electronic equivalent,
144.41(d)	Form 7501	, or its electronic equivalent,
144.42(b)(1)	Form 7501	, or its electronic equivalent,
144.42(b)(2)	Form 7501	, or its electronic equivalent
144.42(b)(3)	Form 7501	, or its electronic equivalent

PART 145—MAIL IMPORTATIONS

■ 53. The general authority citation for Part 145 continues to read as follows:

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

* * * * *

■ 54. In the table below, for each section indicated in the left column, after the

words indicated in the middle column, wherever they appear in the section, add the words indicated in the right column:

145.4(c)	Form 7501	, or its electronic equivalent,
145.12(b)(1)	Form 7501	, or its electronic equivalent
145.12(c)	Form 7501	, or its electronic equivalent
145.12(e)(1)	Form 7501	, or its electronic equivalent

PART 146—FOREIGN TRADE ZONES

Authority: 19 U.S.C. 66, 81a–81u, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States), 1623, 1624.

words indicated in the middle column, wherever they appear in the section, add the words indicated in the right column:

■ 55. The authority citation for Part 146 continues to read as follows:

■ 56. In the table below, for each section indicated in the left column, after the

146.62(a)	or other applicable Customs forms	, or their electronic equivalents
146.62(b)(1)	Form 7501	, or its electronic equivalent,
146.62(b)(2)	Form 7512	, or its electronic equivalent,
146.63(c)(1) (first, second and fourth sentences)	Form 3461	, or its electronic equivalent,
146.63(c)(1) (third sentence)	Form 3461	, or its electronic equivalent
146.70(c)	Form 7501	, or its electronic equivalent,
Appendix to Part 146	CF 7501	, or its electronic equivalent,
Appendix to Part 146	CF 7501s	, or their electronic equivalents,
Appendix to Part 146	CF 3461	, or its electronic equivalent,

PART 148—PERSONAL DECLARATIONS AND EXEMPTIONS

Authority: 19 U.S.C. 66, 1496, 1498, 1624. The provisions of this part, except for subpart C, are also issued under 19 U.S.C. 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States).

■ 58. In the table below, for each section indicated in the left column, after the words indicated in the middle column, wherever they appear in the section, add the words indicated in the right column:

■ 57. The general authority citation for Part 148 continues to read as follows:

* * * * *

148.1(b)	form 4455	, or its electronic equivalent,
148.1(b)	Form 4457	, or its electronic equivalent,
148.1(b)	form 4457	, or its electronic equivalent,
148.6(a)	Form 3299	, or its electronic equivalent,
148.8(b)	Form 4455	, or its electronic equivalent
148.8(c)	Form 4455	, or its electronic equivalent
148.32(b) introductory text	Form 4455	, or its electronic equivalent,
148.37(b)	Form 4455	, or its electronic equivalent,
148.37(c)	Form 4455	, or its electronic equivalent,
148.52(c)	Form 3299	, or its electronic equivalent,
148.53(b)	Form 3299	, or its electronic equivalent,
148.77(b)(1)	Form 3299	, or its electronic equivalent
148.77(b)(2)	Form 3299	, or its electronic equivalent,

PART 151—EXAMINATION, SAMPLING, AND TESTING OF MERCHANDISE

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

words indicated in the middle column, wherever they appear in the section, add the words indicated in the right column:

■ 59. The general authority citation for Part 151 continues to read as follows:

■ 60. In the table below, for each section indicated in the left column, after the

* * * * *

151.11	Form 28	, or its electronic equivalent
151.15(a)	Form 3461, or Customs Form 3461 (ALT)	, or their electronic equivalents,
151.15(a)	Form 3461 or 3461 (ALT)	, or their electronic equivalents
151.15(d)	Form 3461 or 3461 (ALT)	, or their electronic equivalents,

PART 152—CLASSIFICATION AND APPRAISEMENT OF MERCHANDISE

Authority: 19 U.S.C. 66, 1401a, 1500, 1502, 1624,

words indicated in the middle column, wherever they appear in the section, add the words indicated in the right column:

■ 61. The general authority citation for Part 152 continues to read as follows:

■ 62. In the table below, for each section indicated in the left column, after the

* * * * *

152.2	Form 29	, or its electronic equivalent
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PART 158—RELIEF FROM DUTIES ON MERCHANDISE LOST, DAMAGED, ABANDONED, OR EXPORTED

Authority: 19 U.S.C. 66, 1624, unless otherwise noted. Subpart C is also issued under 19 U.S.C. 1563.

words indicated in the middle column, wherever they appear in the section, add the words indicated in the right column:

■ 63. The authority citation for Part 158 continues to read as follows:

■ 64. In the table below, for each section indicated in the left column, after the

158.11(b)(1)	Form 4315	, or its electronic equivalent,
158.13(a)(1)	Form 4315	, or its electronic equivalent
158.13(a)(2)	Form 4315	, or its electronic equivalent
158.23	Form 4315	, or its electronic equivalent

PART 163—RECORDKEEPING

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

words indicated in the middle column, wherever they appear in the section, add the words indicated in the right column:

■ 65. The general authority citation for Part 163 continues to read as follows:

■ 66. In the table below, for each section indicated in the left column, after the

Appendix to Part 163	Form 7501	, or its electronic equivalent,
Appendix to Part 163	Form (CF) 3461	, or its electronic equivalent,
Appendix to Part 163	Form 3229	, or its electronic equivalent,
Appendix to Part 163	CG-5096	, or its electronic equivalent

PART 174—PROTESTS

■ 67. The general authority citation for part 174 continues to read as follows:

Authority: 19 U.S.C. 66, 1514, 1515, 1624.

* * * * *

adding in its place the words “CBP Automated Commercial Environment (ACE) or any other CBP-authorized electronic data interchange system”.

Authority: 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States), 1624, 3314;

* * * * *

§ 174.12 [Amended]

■ 68. Amend § 174.12, in paragraph (c) by removing the word “ACS” and

PART 181—NORTH AMERICAN FREE TRADE AGREEMENT

■ 69. The general authority citation for Part 181 continues to read as follows:

■ 70. In the table below, for each section indicated in the left column, after the words indicated in the middle column, wherever they appear in the section, add the words indicated in the right column:

181.11(b) introductory text	Form 434	, or its electronic equivalent
181.22(b)(1)	Form 434	, or its electronic equivalent
181.47(b)(2)(i)(B)	Form 7501	, or its electronic equivalent,
181.47(b)(2)(ii)(B)	Form 7501	, or its electronic equivalent,
181.47(b)(2)(ii)(D)	Form 7552	, or its electronic equivalent
181.47(b)(2)(iii)(B)	Form 7501	, or its electronic equivalent,
181.53(a)(2)(iii)(B)	Form 7501	, or its electronic equivalent,
181.53(a)(2)(iii)(C)	Form 7501	, or its electronic equivalent,
181.53(a)(3)(i)	Form 7501	, or its electronic equivalent,
181.53(a)(3)(ii)	Form 7501	, or its electronic equivalent,
181.53(a)(3)(iii)	Form 7501	, or its electronic equivalent,
181.53(a)(4)(i)	Form 7501	, or its electronic equivalent,
181.53(a)(4)(ii)	Form 7501	, or its electronic equivalent,
181.53(b)(2) Example	Form 7501	, or its electronic equivalent,
181.53(b)(3) Example	Form 7501	, or its electronic equivalent,
181.53(b)(4)(ii) Example	Form 7501	, or its electronic equivalent,
181.72(a)(3)(i)	Form 28	, or its electronic equivalent,
181.112(a)	Form 4647	, or its electronic equivalent,
181.114(b)(2)	Form 4647	, or its electronic equivalent

PART 191—DRAWBACK

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States), 1313, 1624;

words indicated in the middle column, wherever they appear in the section, add the words indicated in the right column:

■ 71. The general authority citation for Part 191 continues to read as follows:

■ 72. In the table below, for each section indicated in the left column, after the

191.2(c) introductory text	Form 7552	, or its electronic equivalent
191.2(d) introductory text	Form 7552	, or its electronic equivalent
191.91(b)(3)	Form 7501	, or its electronic equivalent

R. Gil Kerlikowske,
Commissioner, U.S. Customs and Border Protection.

Approved: October 5, 2015.

Mark J. Mazur,
Assistant Secretary of the Treasury.

[FR Doc. 2015-25729 Filed 10-9-15; 8:45 am]

BILLING CODE 9111-14-P; 9111-15-P; 9111-16-P; 9111-17-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 107

[Docket No. FDA-2013-N-0067]

Infant Formula: The Addition of Minimum and Maximum Levels of Selenium to Infant Formula and Related Labeling Requirements; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA or we) is confirming the effective date of June 22, 2016, for the final rule that appeared in the **Federal Register** of June 23, 2015. The final rule amended the regulations on nutrient specifications and labeling for infant formula to add the mineral selenium to the list of required nutrients and to establish minimum and maximum levels of selenium in infant formula.

DATES: Effective date of final rule published in the **Federal Register** of June 23, 2015 (80 FR 35834) confirmed: June 22, 2016.

FOR FURTHER INFORMATION CONTACT: Carrie Assar, Center for Food Safety and Applied Nutrition (HFS-850), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 240-402-1451.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 23, 2015 (80 FR 35834), we amended the regulations on nutrient specifications and labeling for infant formula to add 2.0 µg selenium per 100 kilocalories (/100 kcal) as the minimum level of selenium in infant

formulas and 7.0 µg/100 kcal as the maximum level of selenium in infant formulas.

We gave interested persons until July 23, 2015, to file objections or requests for a hearing. We received no objections or requests for a hearing on the final rule. Therefore, we find that the effective date of the final rule that published in the **Federal Register** of June 22, 2016, should be confirmed.

List of Subjects in 21 CFR Part 107

Food labeling, Infants and children, Nutrition, Reporting and recordkeeping requirements, Signs and symbols.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 343, 350a, 371) and under authority delegated to the Commissioner of Food and Drugs, we are giving notice that no objections or requests for a hearing were filed in response to the June 23, 2015, final rule. Accordingly, the amendments issued thereby will become effective June 22, 2016.

Dated: October 7, 2015.

Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2015-25960 Filed 10-9-15; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 524, 556, and 558

[Docket No. FDA-2015-N-0002]

New Animal Drugs; Approval of New Animal Drug Applications; Withdrawal of Approval of a New Animal Drug Application; Change of Sponsor; Change of Sponsor's Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect application-related actions for new animal drug applications (NADAs) and abbreviated new animal drug

applications (ANADAs) during July and August 2015. FDA is also informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable. The animal drug regulations are also being amended to reflect a change of sponsor, a change of sponsor's address, a revised food safety warning, the voluntary withdrawal of approval of an NADA, and a technical amendment. This technical amendment is being made to improve the accuracy of the regulations.

DATES: This rule is effective October 13, 2015, except for the amendment to 21 CFR 558.460, which is effective October 23, 2015.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-5689, george.haibel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during July and August 2015, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday. Persons with access to the Internet may obtain these documents at the CVM FOIA Electronic Reading Room: <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/CVMFOIAElectronicReadingRoom/default.htm>. Marketing exclusivity and patent information may be accessed in FDA's publication, Approved Animal Drug Products Online (Green Book) at: <http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/default.htm>.