(d) Fees for overflights through U.S.-controlled airspace covered by a written FAA agreement or other binding arrangement are charged according to the terms of that agreement or arrangement unless the terms are silent on fees.

§ 187.53 Calculation of overflight fees.

(a) The FAA assesses a total fee that is the sum of the Enroute and Oceanic calculated fees.

(1) *Enroute fee.* The Enroute fee is calculated by multiplying the Enroute rate in paragraph (c) of this section by the total number of nautical miles flown through each segment of Enroute airspace divided by 100 (because the Enroute rate is expressed per 100 nautical miles).

(2) *Oceanic fee.* The Oceanic fee is calculated by multiplying the Oceanic rate in paragraph (c) of this section by the total number of nautical miles flown through each segment of Oceanic airspace divided by 100 (because the Oceanic rate is expressed per 100 nautical miles).

(b) Distance flown through each segment of Enroute or Oceanic airspace is based on the great circle distance (GCD) from the point of entry into U.S.-controlled airspace to the point of exit from U.S.-controlled airspace based on FAA flight data. Where actual entry and exit points are not available, the FAA will use the best available flight data to calculate the entry and exit points.

(c) The rate for each 100 nautical miles flown through Enroute or Oceanic airspace is:

Time period	Enroute rate	Oceanic rate
January 1, 2017 to January 1, 2018	58.45	23.15
January 1,2018 to January 1, 2019	60.07	24.77
January 1, 2019 and Beyond	61.75	26.51

(d) The formula for the total overflight fee is:

$$Rij = E*DEij/100 + O*DOij/100$$

Where:

Rij = the total fee charged to aircraft flying between entry point i and exit point j.

DEij = total distance flown through each segment of Enroute airspace between entry point i and exit point j.

DOij = total distance flown through each segment of Oceanic airspace between entry point i and exit point j.

E and O = the Enroute and Oceanic rates, respectively, set forth in paragraph (c) of this section.

(e) The FAA will review the rates described in this section at least once every 2 years and will adjust them to reflect the current costs and volume of the services provided.

§ 187.55 Overflight fees billing and payment procedures.

(a) The FAA will send an invoice to each user when fees are owed to the FAA. If the FAA cannot identify the user, then an invoice will be sent to the registered owner. Users will be billed at the address of record in the country where the aircraft is registered, unless a billing address is otherwise provided.

(b) The FAA will send an invoice if the monthly (based on Universal Coordinated Time) fees equal or exceed $400.

(c) Payment must be made by one of the methods described in § 187.15(d).

Appendix B to Part 187—[Removed and Reserved]

■ 5. Remove and reserve Appendix B to Part 187.

Issued under authority provided by 49 U.S.C. 106(f) and 45302, in Washington, DC, on November 7, 2016.

Michael P. Huerta,

Administrator.

[FR Doc. 2016–28589 Filed 11–28–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 1005, and 1271

[Docket No. FDA–2016–N–1487]

RIN 0910–AH41

Submission of Food and Drug Administration Import Data in the Automated Commercial Environment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing a final rule/regulation to establish requirements for the electronic filing of entries of FDA-regulated products in the Automated Commercial Environment (ACE) or any other electronic data interchange (EDI) system authorized by the U.S. Customs and Border Protection Agency (CBP), in order for the filing to be processed by CBP and to help FDA in determining admissibility of that product. ACE is a commercial trade processing system operated by CBP that is designed to implement the International Trade Data System (ITDS), automate import and export processing, enhance border security, and foster U.S. economic security through lawful international trade and policy. FDA is a Partner Government Agency (PGA) for purposes of submission of import data in ACE. As of July 23, 2016, ACE became the sole EDI system authorized by CBP for entry of FDA-regulated articles into the United States. We also updated certain sections of FDA regulations related to imports. This rule will facilitate effective and efficient admissibility review by the Agency and protect public health by allowing FDA to focus its limited resources on those FDA-regulated products being imported or offered for import that may be associated with a greater public health risk.

DATES: This rule is effective December 29, 2016.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the ''Search'' box and follow the prompts, and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: *With regard to the final rule:* Ann M. Metayer, Office of Regulatory Affairs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4338, Silver Spring, MD 20993–0002, 301–796–3324, *Ann.Metayer@fda.hhs.gov.*

With regard to the information collection: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St.,

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SUPPLEMENTARY INFORMATION:

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I. Executive Summary

A. Purpose of the Final Rule

The rule requires that certain data elements material to our import admissibility review be submitted in ACE or any other CBP-authorized EDI system, at the time of entry. This action will facilitate automated ''May Proceed'' determinations by us for low-risk FDA-regulated products which, in turn, will allow the Agency to focus our limited resources on products that may be associated with a greater public health risk. We also made technical revisions to certain sections of FDA regulations to make updates and provide clarifications.

B. Summary of the Major Provisions of the Final Rule

This rule adds subpart D to part 1 of 21 CFR chapter I (21 CFR part 1) to require that certain data elements be submitted in ACE or any other CBP-authorized EDI system, at the time of entry in order to facilitate admissibility review by the Agency of FDA-regulated products being imported or offered for import into the United States. Submission of these data elements in ACE will help us to more effectively and efficiently make admissibility determinations for FDA-regulated products by increasing the opportunity for automated review by FDA's Operational and Administrative System for Import Support (OASIS). We also added § 1.81 to the final rule to clarify that FDA may reject an import filing for failure to provide the complete and accurate information required in the rule.

We made technical revisions to certain sections of 21 CFR chapter I to update them. We revised 21 CFR 1.83 and 1005.2 to update the definition of owner or consignee in order to make that definition consistent with Title 19 of the U.S. Code. We also revised § 1.90 to allow FDA to provide notice of sampling directly to an owner or consignee. Additionally, we revised § 1.94 to clarify that written notice can be provided electronically by FDA to owners or consignees of FDA actions to refuse and/or subject certain products to administrative destruction. Under § 1.94, owners or consignees receive notice that FDA intends to take a certain action against an FDA-regulated product that is being imported or offered for import and the owner or consignee will have an opportunity to introduce testimony to the Agency in opposition to such action. We also amended 21 CFR 1271.420 to make clear that, unless otherwise exempt, importers of record of human cells, tissues or cellular or tissue-based products (HCT/Ps) that are regulated solely under section 361 of the Public Health Service Act (PHS Act) (42 U.S.C. 264) and part 1271 (21 CFR part 1271) would be required to submit the applicable data elements included in this rule in ACE.

The final rule does not include certain aspects of the proposed rule that were opposed by many who submitted comments. For example, the final rule no longer includes FDA Value, FDA Quantity, Entity Contact Information other than for the importer of record, name and address of the ACE filer for tobacco products, and the Investigational New Drug Application Number for device-drug combination products as data elements that must be submitted in ACE at the time of entry. We have also removed, at our own initiative, the Drug Listing Number requirement for those human drugs that are regulated by FDA's Center for Biologics Evaluation and Research (CBER).

C. Legal Authority

The legal authority for this rule includes sections 536, 701, and 801 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360mm, 371, and 381, respectively), and sections 351, 361, and 368 of the PHS Act (42 U.S.C. 262, 264, and 271, respectively).

D. Costs and Benefits

The costs of complying with this regulation are between $27 million and $69 million per year (using 3 and 7 percent discount rates). The annualized cost savings to the entire industry cannot be fully quantified because of the lack of certain data currently available to the Agency. Partially quantifiable cost savings are estimated to range from $2.6 million to $43.4 million (using 3 and 7 percent discount rates).

II. Table of Abbreviations and Acronyms Commonly Used in This Document

Abbreviation/acronym	What it means
ACE	Automated Commercial Environment or any other CBP-authorized EDI system.
ACE filer	The person who is authorized to submit an electronic import entry for an FDA-regulated product in ACE.
ACS	Automated Commercial System—the predecessor CBP-authorized EDI system to ACE.
Agency	U.S. Food and Drug Administration.
CATAIR	Customs and Border Protection and Trade Automated Interface Requirements.
CBP	U.S. Customs and Border Protection Agency.
CBER	FDA Center for Biologics Evaluation and Research.
CDER	FDA Center for Drug Evaluation and Research.
CDRH	FDA Center for Devices and Radiological Health.
CTP	FDA Center for Tobacco Products.
CVM	FDA Center for Veterinary Medicine.
EDI	Electronic Data Interchange.
FDA	U.S. Food and Drug Administration.
FDASIA	Food and Drug Administration Safety and Innovation Act.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
HCT/P	Human cells, tissues, or cellular or tissue-based products.

Abbreviation/acronym	What it means
ITDS	International Trade Data System.
OASIS	FDA's Operational and Administrative System for Import Support.
PGA	Partner Government Agency in ACE.
PHS Act	Public Health Service Act.
We, Our, Us	U.S. Food and Drug Administration.

III. Background

In the **Federal Register** of July 1, 2016 (81 FR 43155), FDA proposed a rule to require that certain data elements material to our import admissibility review be submitted in ACE at the time of entry. We also proposed to make technical revisions to certain sections of FDA regulations to make updates and provide clarifications. Interested parties were given 60 days to submit comments on the proposed rule to the public docket.

We received 13 comment letters on the proposed rule by the close of the comment period, each containing one or more comments on one or more issues. These comments were submitted to the public docket by trade organizations, the trade industry, and the public. The final rule has been revised in response to comments received on the proposed rule. Our responses are discussed in section V. As discussed earlier in this document, we also decided, on our own initiative, to not include one required data element in the final rule. Additionally, the final rule includes several minor editorial revisions. Substantive changes from the proposed rule to the final rule are summarized in table 1.

TABLE 1—SUBSTANTIVE CHANGES FROM THE PROPOSED RULE TO THE FINAL RULE

21 CFR section in final rule	Description of change from proposed rule
1.71	Definitions. • Removed definition of ''combination product'' because Investigational New Drug Application Number (§ 1.76(h) in the proposed rule) removed. • Removed definition of ''import line'' because FDA Value (§ 1.72(a)(3) in the proposed rule) removed.
1.72	Data elements that must be submitted in ACE for articles regulated by FDA. • Removed FDA Value (§ 1.72(a)(3) in the proposed rule). • Removed FDA Quantity (§ 1.72(a)(4) in the proposed rule). • Removed Name, telephone, and email address of any one of the persons related to the importation of the product which may include the manufacturer, shipper, importer of record, or Deliver to Party (§ 1.72(b)(1) in the proposed rule). • Added submission of the full intended use code (§ 1.72(a)(3)); not in the proposed rule.
1.73	Food. • Removed requirement to submit FDA Value under § 1.72(a)(3) for food (§ 1.73(a) in the proposed rule). • Removed requirement to provide Food Canning Establishment Number and the Submission Identifier, and can dimensions or volume for low-acid canned foods and acidified foods imported or offered for import for laboratory analysis only, when such foods will not be taste tested or otherwise ingested
1.76	Medical Devices. • Removed requirement to submit Investigational New Drug Application Number (§ 1.76(h) in the proposed rule).
1.78	Biological products, HCT/Ps, and related drugs and medical devices. • Removed requirement to submit Drug Listing Number (removed from § 1.78(d) in the proposed rule).
1.79	Tobacco products. • Excludes products solely intended for further manufacturing and investigational tobacco products from requirement. Requires submission of a commercial name for any such tobacco product that does not have a specific brand name (§ 1.79(a) of the proposed rule). • Removed name and address of the ACE filer for any entry that includes an article that is a tobacco product (§ 1.79(b) of the proposed rule).
1.81	Rejection of Entry Filing. • Clarifies that FDA may reject an entry filing for failure to provide complete and accurate information as required in the final rule; not included in the proposed rule.

IV. Legal Authority

We have the legal authority under the FD&C Act and the PHS Act to regulate foods, cosmetics, drugs, biological products, medical devices, and tobacco products being imported or offered for import into the United States (sections 701 and 801 of the FD&C Act; section 351 of the PHS Act). We also have the legal authority to regulate the importation of radiation-emitting electronic products (section 536 of the FD&C Act).

Additionally, section 361 of the PHS Act authorizes FDA to make and enforce such regulations as it judges necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States or from State to State. FDA has issued regulations in part 1271 to regulate HCT/Ps. HCT/Ps that do not meet the criteria listed in § 1271.10(a) for them to be regulated solely under section 361 of the PHS Act and the regulations in part 1271 are regulated as drugs, devices, and/or biological products under the FD&C Act and/or section 351 of the PHS Act and must follow applicable regulations, including the applicable regulations in part 1271. FDA has determined that improving the efficiency of admissibility determinations for HCT/Ps, thus improving the allocation of Agency resources, is necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries. We are therefore relying on the authority of section 361 of the PHS

Act in the amendments to § 1271.420. Authority for enforcement of section 361 of the PHS Act is provided by section 368 of the PHS Act.

We are also issuing this rule under authority granted to FDA by section 801(r) of the FD&C Act, added by section 713 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) (FDASIA). Title VII of FDASIA provides FDA with important new authorities to help the Agency better protect the integrity of the drug supply chain. Section 801(r) of the FD&C Act authorizes FDA to require, as a condition of granting admission to a drug imported or offered for import into the United States, that the importer of record electronically submit information demonstrating that the drug complies with the applicable requirements of the FD&C Act. This information may include:

- Information demonstrating the regulatory status of the drug, such as the new drug application, the abbreviated new drug application, investigational new drug, or drug master file number;
- facility information, such as proof of registration and the unique facility identifier; and
- any other information deemed necessary and appropriate by FDA to assess compliance of the article being offered for import.

Section 701(a) of the FD&C Act authorizes the Agency to issue regulations for the efficient enforcement of the FD&C Act, while section 701(b) of the FD&C Act authorizes FDA and the Department of the Treasury to jointly prescribe regulations for the efficient enforcement of section 801 of the FD&C Act. This rule is being jointly prescribed by FDA and the Department of the Treasury, with the exception of the provisions of the rule related to the importation of HCT/Ps which are regulated solely under section 361 of the PHS Act and part 1271 and the importation of radiation-emitting electronic products which are regulated under section 536 of the FD&C Act; neither of these provisions will be issued for the efficient enforcement of section 801 of the FD&C Act.

V. Comments on the Proposed Rule and FDA Response

A. Introduction

Sections V.B and V.C contain summaries of the relevant portions of the responsive comments and the Agency's responses to those comments. We have numbered each comment to help distinguish between different comments. We have grouped similar comments together under the same number, and, in some cases, we have separated different issues discussed in the same comment and designated them as distinct comments for purposes of our responses. The number assigned to each comment or comment topic is purely for organizational purposes and does not signify the comment's value or importance or the order in which comments were received.

The Agency also received a number of comments that were not responsive to the content of the proposed rule and therefore were not considered in its final development.

B. Description of General Comments and FDA Response

A number of comments made general remarks supporting or opposing the proposed rule without focusing on a particular proposed provision. In the following paragraphs, we discuss and respond to such general comments.

(Comment 1) We received a comment expressing concern that several of the data elements in the proposed rule appear to require information that is already being provided in ACE pursuant to CBP requirements. We also received comments that many of the required data elements represent information that is already available to the Agency.

(Response 1) FDA acknowledges that some of the required data elements in this rule may appear similar to CBP data requirements in ACE. The rule, however, only contains those data elements that provide additional information that is material to FDA's initial admissibility review of an FDA-regulated article that is being imported or offered for import. Where information is already being collected by CBP and is acceptable for FDA admissibility review purposes, we did not include those data elements in the rule. For example, CBP collected FDA manufacturer and shipper, and ultimate consignee information in the Automated Commercial System (ACS), the predecessor CBP-authorized EDI system to ACE, to assist FDA in admissibility review of FDA-regulated products. We determined that the information CBP collects in ACE for manufacturer and shipper and Deliver to Party is sufficient for our purposes so we did not include those data elements in this rule.

We acknowledge that FDA may have access to some of the information which is required by the rule to be submitted by ACE filers at the time of entry. However, ACE filers and importers are in a better position to know the identity and characteristics of the particular article being imported or offered for import. For example, the importer should be aware of what Drug Listing Number is applicable to a particular drug article, what the applicable Food Canning Establishment Registration (FCE) number, Submission Identifier (SID), or can dimensions or volume are applicable to a particular low-acid canned food, or what the brand name is of a particular tobacco product.

In addition, submission of the required data elements in the final rule will assist FDA in expediting the initial screening and further review of an entry, and can significantly increase the likelihood that an entry line will receive an automated ''May Proceed.'' Historically, when these data fields are inaccurate or incomplete, these entries must be manually reviewed for an admissibility determination by FDA. Entries are delayed, sometimes significantly, while an FDA-reviewer either searches for that information in our data systems or requests followup documentation from the importer of record. An automated review to determine whether an article ''May Proceed'' is much faster and less resource intensive for both FDA and the importer.

(Comment 2) Several commenters requested that FDA make some or all of the required data elements in the proposed rule optional or, in the alternative, allow ACE filers to submit ''UNK'' representing ''unknown'' in ACE for those data elements. These commenters stated that the data elements are not always known or available to the ACE filer at the time entry is electronically filed in ACE. They expressed concern that CBP would not process the entry filing in ACE if all the required data elements are not submitted at time of entry. But, if the data is optional or if ''UNK'' is allowed to be submitted for a required data element, they asserted, CBP would process the entry and transmit the entry data to FDA's OASIS system. These commenters recognized that an FDA ''May Proceed'' would not issue until the missing data was provided by the ACE filer but that CBP may issue a delivery authorization to allow the goods to move from the port to the importer's premises in the interim. This would, they believe, avoid a backlog of cargo at the port and the cost of storage and demurrage as an ACE filer waited to receive the information from the importer.

(Response 2) As discussed in Response 6 in this document, we are requiring submission of intended use codes in ACE in the final rule but are allowing ACE filers to submit ''UNK'' as the intended use code in ACE at the time of entry. We decline, however, to accept ''UNK'' for any other required

data element in the final rule. As stated in the proposed rule, the number of import lines that include FDA-regulated articles continues to grow steadily every year and this is posing challenges to the Agency in enforcing sections 536 and 801 of the FD&C Act and sections 351, 361, and 368 of the PHS Act. The number of import lines in 2015 that included an FDA-regulated article exceeded 35 million. In ACS, where submission of data elements was optional, the number of submissions varied depending on commodity. As stated previously in this document, where certain data was missing or inaccurate, entries had to be manually reviewed for an admissibility determination by FDA and entries were sometimes significantly delayed. In the final rule, we are requiring only certain data elements that we have determined to be material to our import admissibility review be submitted in ACE at the time of entry. The purpose of the rule is to facilitate automated ''May Proceed'' determinations by us for low-risk FDA-regulated products which, in turn, will allow the Agency to focus our limited resources on products that may be associated with a greater public health risk. An automated review to determine whether an article ''May Proceed'' is much faster and less resource intensive for FDA and the importer than a manual review. As expected, we have seen a decrease in the FDA processing time for both automated and manual ''May Proceed'' determinations since ACE became the sole CBP-authorized EDI system in July 2016. The average time for the OASIS system to process an import entry submitted in ACS from August 27 to October 22, 2015, and issue an automated ''May Proceed'' determination was approximately 7.1 minutes which has been reduced to approximately 2 minutes in ACE from August 27 to October 22, 2016. The average time for an FDA-reviewer to manually review and issue a ''May Proceed'' determination in ACS from August 27 to October 22, 2015, was about 28 hours and that has been reduced to under 2 hours in ACE from August 27 to October 22, 2016. As a result of a more streamlined import process, the rule is expected to lead to a more effective use of FDA and importer resources, and more efficient enforcement of the FD&C Act and the PHS Act for imported products.

In addition, we expect that, after the initial adjustment phase, submission of the data elements required by the rule will become incorporated into the business practices of importers and customs brokers. Persons wishing to import FDA-regulated products into the United States are required to file the entry documentation or data required by CBP and FDA at the time of entry in ACE in order to secure the release of an FDA-regulated article from CBP custody (19 CFR 142.3). Entry and entry summary documentation that is filed electronically in ACE must be certified by the importer of record or his/her duly authorized customs broker as being true and correct to the best of his/her knowledge. A certified electronic transmission is binding in the same manner and to the same extent as a signed document (19 CFR 141.61(a)(2)).

Approximately 98 percent of importers use customs brokers to file their entries containing FDA-regulated products subject to the final rule. Customs brokers are required to exercise due diligence in preparing or assisting in the preparation of records for import entries (19 CFR 111.29). We expect that importers and customs brokers will adapt their business practices to provide the required data elements in ACE at the time of entry in order to secure the release of an FDA-regulated article from CBP custody and submission of these data elements will become routine.

(Comment 3) Some commenters requested that we use the term ''transmission of data elements in ACE'' instead of ''submission of data elements in ACE'' by ACE filers suggesting that FDA distinguish between the importer (as the provider of information) and the customs broker/filer (as the transmitter of the information provided by the importer). One comment suggested that we adopt the distinction between ''submitter'' and ''transmitter'' that appears in the Prior Notice of Imported Food regulation (21 CFR part 1, subpart I).

(Response 3) We decline to make that change. ''Submission'' is the term used in CBP regulations to characterize the electronic submission to ACE of the entry summary documentation or data for preliminary review or of entry documentation or data for other purposes (19 CFR 141.0a(c)). Further, as stated previously, approximately 98 percent of importers use customs brokers to file their entries containing FDA-regulated products subject to the rule; the other 2 percent file these entries themselves. The obligations of customs brokers extend beyond the mere electronic transmission of data received for transmission to CBP (see definition of ''customs business'' in 19 CFR 111.1).

It should also be noted that this rule does not address or impact the current import entry review process for food articles requiring prior notice which has been operationally transitioned from ACS to ACE. The prior notice information required under § 1.281 is currently submitted in ACE or the FDA Prior Notice System Interface (PNSI) before the arrival of a food article in the United States. The different roles of transmitter and submitter for prior notice are tied to the existence of two systems for filing prior notice and the particular roles of filers in that process. We do not see a benefit in applying those concepts to the process of filing entry for FDA-regulated products that are not subject to prior notice.

(Comment 4) Some commenters expressed doubts that submission of additional data in ACE for FDA-regulated products will result in increased efficiencies in FDA admissibility review particularly an increase in automated ''May Proceed'' determinations by the Agency.

(Response 4) Although we do not at this time have statistics on the numbers of automated ''May Proceed'' determinations that will result from implementation of the rule, we have already seen a substantial decrease in average FDA processing times for both automated and manual ''May Proceed'' determinations since ACE became the sole CBP-authorized EDI system in July 2016. As we and the trade industry continue to adjust to the new system and various technological issues with ACE that have arisen during the transition to ACE are addressed, we expect these processing times to continue to improve.

C. Specific Comments and FDA Response

For some of the proposed data elements and other requirements, FDA either did not receive comments or the comments were generally supportive. Unless otherwise noted, FDA has kept these requirements in the final rule for the reasons given in the proposal.

1. Approval or Clearance Status of FDA-Regulated Medical Products

In the Notice of Proposed Rulemaking, we invited comments on the advantages, disadvantages, and feasibility of requiring the submission of data elements related to the approval or clearance status of FDA-regulated medical products. We proposed to require the submission at the time of entry of application numbers for those articles that are the subject of such applications. In particular, we invited comment on whether the submission of these data elements would help us achieve our goals of facilitating admissibility review and focusing our

resources on those products that may be associated with a serious public health risk to consumers.

We received several comments supportive of our position and none of the comments suggested revising the provisions in the proposed rule related to the submission of application numbers. We are finalizing those provisions without change.

2. Active Pharmaceutical Ingredient Data Elements

We also invited comments on the advantages, disadvantages, and feasibility of requiring what are now optional active pharmaceutical ingredient (API) data elements for finished human and animal drugs contained in the PGA Message Set (*e.g.,* name of the API, the amount and unit of measure of the API, and the name of the manufacturer of the API in the finished drug) to be submitted in ACE at the time of entry.

(Comment 5) Several comments asserted that requiring submission of these API data elements in ACE at the time of filing entry would create a significant burden on industry. These commenters urged FDA to leave the API data elements as optional submissions in ACE, so that an ACE filer could choose to transmit the information if available at time of entry. The comments noted that by keeping the API data elements optional, CBP would be able to process the entry for a drug product, even if the API information were not transmitted in ACE at the time of entry. If, however, FDA determines further evaluation is necessary, FDA could then request API information during our review of the entry for admissibility.

(Response 5) In response to these comments, we have decided to keep the API data elements as optional submissions in ACE at the time of entry. Although these data elements will remain optional, FDA strongly encourages ACE filers to submit the API data elements at the time of entry to facilitate FDA's admissibility review. These API data elements provide us with information that may be material to our admissibility review for drug products. For example, submission of these API data elements would help FDA assess whether a finished dosage form drug that is being imported or offered for import appears to be adulterated and may be subject to refusal of admission under section 801(a) of the FD&C Act. If an API has not been manufactured in compliance with Current Good Manufacturing Practices (CGMP), it is deemed adulterated within the meaning of section 501(a)(2)(B) of the FD&C Act because the methods used in, or the facilities or controls used for, the drug's manufacture, processing, packing or holding did not conform to, or were not operated or administered in conformity with, CGMP requirements. A finished dosage form drug is deemed adulterated if it contains an API that is adulterated. Drugs that appear to be adulterated are subject to detention and refusal under section 801(a) of the FD&C Act. FDA has placed a number of foreign API suppliers on Import Alert 66–40, which may subject their APIs to detention without physical examination, because the firms have not met CGMPs. As a consequence, FDA has refused admission of drug products that have been manufactured using APIs on Import Alert 66–40, under section 801(a)(3) of the FD&C Act.

In addition, if a foreign-manufactured API was used in a drug product that is the subject of an approved application under section 505 or 512 of the FD&C Act (21 U.S.C. 355 or 360b), the API manufacturer must be an acceptable source listed in the approved NDA or ANDA for human drugs (*see, e.g.,* 21 CFR 314.50(d)(1)(i)) or in the approved NADA or ANADA for animal drugs (*see, e.g.,* 21 CFR 514.1(b)(5)(i)). Submitting the API data elements in ACE for a drug product that is the subject of an approved application would facilitate FDA's assessment of whether the finished dosage form drug complies with section 505 or 512.

If ACE filers submit the optional API data elements in ACE, it likely will increase the likelihood that the import entry will receive an automated ''May Proceed'' determination from the Agency. If the API data elements are not submitted in ACE, the entry may receive a manual review and the FDA reviewer may request that the importer provide API information for the finished dosage product.

3. Intended Use Code and Disclaimer

FDA invited comments on the advantages, disadvantages, and feasibility of the Agency requiring the submission of the following data elements in ACE at the time of entry: (1) An intended use code for the FDA-regulated article being imported or offered for import and (2) a disclaimer indicating that that the article is not currently regulated by FDA or that FDA does not currently have any requirements for submission of data for importation of that article per Agency guidance.

a. *Intended use code.* We received several comments supporting inclusion of intended use codes in the final rule. Historically, FDA derived intended use information for the purposes of FDA's admissibility review from the free text information submitted in the CBP-required product description field in ACS. Intended use codes were developed for ACE in the PGA message set to provide a consistent, systematic approach to collection of certain intended use information about articles that are being imported or offered for import into the United States. These codes standardize the data input for computer processing in ACE. If FDA needs a particular intended use code (IUC) for the ACE system to identify what FDA data elements are needed for a particular FDA-regulated product, the proposed IUC is submitted to CBP for inclusion in Appendix R to the Customs and Border Protection and Trade Automated Interface Requirements (CATAIR).

We added § 1.72(a)(3) to the final rule to require that a full IUC be submitted in ACE at the time of entry for each FDA-regulated article that is being imported or offered for import into the United States. Appendix R defines a full IUC as consisting of a base code that designates the general use intended for the article and a subcode, if applicable, that designates the specific use intended for the article.

(Comment 6) One commenter supported mandatory intended use codes and several commenters requested that IUCs be optional data submissions at the time of entry in ACE or, in the alternative, that FDA continue to allow ACE filers to submit ''UNK'' as the IUC in ACE at the time of entry. These commenters assert that the intended use of an article is often not known at the time of entry and that if FDA needs this information, it can be provided at a later date.

(Response 6) Because IUCs are such an integral part of the ACE system regarding the identification of those required data elements in the rule applicable to a particular article that must be submitted in ACE at the time of entry, we decline to make IUCs optional. After considering the comments, we have decided, however, to continue to allow submission of the intended use code ''UNK'' for FDA-regulated articles. ''UNK'' is currently listed as an IUC in Appendix R of the CATAIR. Operationally, submission of ''UNK'' will not trigger the ACE system to identify all of the FDA data elements that are required to be submitted for a particular FDA-regulated article whereas submission of the specific IUC applicable to that article will trigger the ACE system to identify the required data

fields and reject the filing if the required data is not submitted.

If ''UNK'' is submitted as the IUC for the article, the ACE filer is still responsible for submitting the other required data elements in this rule that are applicable to that article, in ACE at the time of entry. If those other data elements are not submitted in ACE at the time of entry, the entry may be transmitted by ACE to OASIS for FDA's admissibility review but FDA may decide to not perform an admissibility review until those data elements have been submitted. We have added § 1.81 to the final rule to make clear that FDA may reject any entry filing that does not contain the complete and accurate information required by the rule without performing an admissibility review. If FDA rejects an entry filing under § 1.81, the ACE filer will need to withdraw the entry in ACE and resubmit the entry with the complete and accurate information required under the rule in order to have FDA perform an admissibility review of that entry. ACE filers also need to be aware that submitting ''UNK'' as the intended use code will, in most cases, subject the entry to a manual review for admissibility provided the entry filing is not rejected by FDA.

b. *Disclaimer.* By submitting a disclaimer in ACE at the time of entry, an ACE filer indicates that the article being imported or offered for import is not currently regulated by FDA or that FDA does not currently have any requirements for submission of data for importation of that article per Agency guidance.

(Comment 7) Several commenters expressed the opinion that the current disclaimer procedures in ACE should not be changed.

(Response 7) After consideration of the comments received, we have decided not to include FDA-required disclaimer data elements in the final rule. ACE filers can continue to submit disclaimers in ACE at the time of entry following current procedures.

4. General Data Elements for FDA-Regulated Commodities

a. *FDA country of production.* The FDA Country of Production identifies the country where an FDA-regulated article last underwent any manufacturing or processing but only if such manufacturing or processing was of more than a minor, negligible, or insignificant nature. This differs from the CBP country of origin which uses a substantial transformation test. When an article has undergone a ''substantial transformation'' in a different country, CBP requires that the country of origin be changed to the country where the substantial transformation has taken place. Substantial transformation occurs in the country where the article acquired the name, character or intended use that matches the article identified in the entry.

CBP collected FDA Country of Production in ACS to assist FDA in making admissibility decisions for FDA-regulated products.

(Comment 8) Some commenters requested additional guidance on what FDA considers to be manufacturing or processing of more than a minor, negligible, or insignificant nature. One commenter suggested that FDA consider issuing a ''positive'' list of manufacturing activities or processes that definitively impart ''FDA Country of Production'' status or alternatively issue a list of manufacturing or processing activities that are considered by the Agency to be minor, negligible or insignificant.

(Response 8) Whether the manufacturing or processing of a particular FDA-regulated article is of more than a minor, negligible or insignificant nature is dependent on the facts of each particular case which include the specific manufacturing or processing activities involved as well as the type of commodity that is being affected by those activities. We have provided below some examples to illustrate activities FDA would consider to be more than minor, negligible, or insignificant which would impact the FDA Country of Production.

For example:

- If an FDA-regulated article undergoes further manufacturing/processing at a facility, such as encapsulating a drug, the country where the facility that performed the additional manufacturing/processing is located is considered to be the FDA Country of Production.
- Conversely if an article was not further manufactured/processed by a facility, such as repacking retail packages into a different master carton for shipping, the country where the facility that performed this repacking is located would not be considered to be the FDA Country of Production.

We will also consider the issuance of additional guidance in the future as resources allow.

(Comment 9) One comment requested clarification regarding the application of FDA Country of Production to Foreign Trade Zone (FTZ) operations. The Commenter suggested revising the FDA Country of Production data element by adding this sentence: ''For articles imported from foreign-trade zones, if the article has undergone manufacturing in the foreign-trade zone, the FDA Country of Production is the United States for FDA import purposes.''

(Response 9) FDA recognizes that the FDA Country of Production will be the United States if more than minimal, negligible, or insignificant manufacture or processing occurs in an FTZ but we decline to make the suggested revision because it is unnecessary.

b. *The complete FDA product code.* CBP also collected the Complete FDA Product Code in ACS to assist FDA in making admissibility decisions for FDA-regulated products.

(Comment 10) Some commenters supported the requirement for submission of the Complete FDA Product Code but requested clarification regarding the requirement that the code '' . . . must agree with the invoice description of the product. '' They expressed concern that ''agreement'' could be interpreted in various ways by both FDA-reviewers and industry resulting in unintended and unnecessary detentions or delays for completion of admissibility determinations. For example, ''agreement'' with the invoice description could be understood as requiring a partial or complete verbatim match between the invoice description and the product code.

(Response 10) FDA does not intend for the invoice description and the Complete FDA Product Code to be identical. In order to clarify this requirement, we have revised the language in the rule to require that the Complete FDA Product Code be ''consistent'' with the invoice description.

c. *FDA value.* We proposed to require that the total value of an entry as required by CBP or the total value of the article(s) in each import line be submitted at the time of entry in ACE and invited comments on the advantages, disadvantages, and feasibility of allowing the ACE filer to submit the total value of the entry or the total value apportioned to the article(s) in each import line. In particular, we invited comment on whether the submission by an ACE filer of the value apportioned to the article(s) in an import line in ACE at the time of entry would help us achieve our goals of facilitating admissibility review and focusing our resources on those products that may be associated with a serious public health risk to consumers.

(Comment 11) We received several comments that expressed confusion over the products that would be subject to the proposed FDA Value requirement, as well as the ''value'' that was required to be submitted in ACE for an entry that

includes an FDA-regulated article. The commenters suggested that the Agency accept the total value of an entry required by CBP without the need to break-out the value of each import line. Pro-rating the value to each import line, they assert, can be a cumbersome, time intensive process with no practical value to FDA for typical entries containing FDA-regulated products which may have many separate lines.

(Response 11) FDA will accept the total value of an entry required by CBP and, therefore, we have decided not to finalize § 1.72(a)(3) in the proposed rule. ACE filers, however, will continue to have the option to submit the total value of the article(s) in each import line.

d. *FDA quantity.* FDA proposed to require submission of the quantity of the FDA-regulated article(s) in each import line at the time of entry in ACE. FDA Quantity would include the quantity of each layer/level of packaging of the article(s), the unit of measure which is the description of each type of package, and the volume and/or weight of each of the smallest of the packaging units. The quantity would be required to be submitted in decreasing size of packing unit (starting with the outermost/largest package to the innermost/smallest package). We invited comments on the advantages, disadvantages, and feasibility of requiring an ACE filer to submit the FDA quantity of the article(s) in each import line in ACE at the time of entry. In particular, we invited comment on whether the submission by an ACE filer of the FDA quantity of the article(s) in an import line would help us achieve our goals of facilitating admissibility review and focusing our resources on those products that may be associated with a serious public health risk to consumers.

(Comment 12) We received several comments that this level of detail for quantity as an ''across-the-board'' data requirement would entail significant data input on the part of ACE filers and would not enhance admissibility review by FDA.

(Response 12) In response to the comments we received we have decided not to finalize § 1.72(a)(4) of the proposed rule which would have required FDA Quantity to be submitted in ACE at the time of entry. ACE filers, however, will still have the option of submitting this information.

e. *Entity contact information.* In the proposed rule, we proposed to require that the name, telephone, and email address of any one of the persons related to the importation of the article(s) in the entry, which may include the manufacturer, shipper, importer of record, or Deliver to Party, be submitted in ACE at the time of entry. We invited comments on the advantages, disadvantages, and feasibility of requiring an ACE filer to submit the name, telephone, and email address of any one of the persons related to the importation of the article(s) in the entry, in ACE at the time of entry. In particular, we invited comment on whether the submission by an ACE filer of this information would help us achieve our goals of facilitating admissibility review and focusing our resources on those products that may be associated with a serious public health risk to consumers.

(Comment 13) We received several comments opposing this provision in the proposed rule. One commenter expressed concern that the proposed entity contact information was unnecessarily duplicative of the contact information the Agency was proposing to require for the importer of record. In addition, the commenter suggested that the email and phone of the importer of record should only be required at the header level, not for each import line.

(Response 13) After review of the comments we have decided to require email address and phone for the importer of record only. The contact information for other parties to the shipment, which may expedite the entry review process, can be provided to the Agency at the option of the ACE filer.

However, FDA does not determine what information is submitted at the header level, CBP makes those determinations. In addition, the burden to input the same data repeatedly on the same entry may be ameliorated through software programming.

5. Food

Low-acid canned food. We proposed that the Food Canning Establishment (FCE) Number, the Submission Identifier (SID), and the can dimensions or volume (*e.g.,* pouches and bottles) be required submissions in ACE at the time of entry.

(Comment 14) One comment asked us to clarify whether the FCE number, SID, and can dimensions or volume information will be required for LACF products that are imported for research and testing at laboratories, but that are not sold or marketed in the United States and are not intended for consumption in the United States.

(Response 14) We do not believe we will generally need the FCE number, SID, and can dimensions or volume to effectively identify LACF products that are being imported or offered for import for laboratory analysis only, when such foods will not be consumed by humans or animals. Consequently, we have revised § 1.73(b). Under the final rule, § 1.73(b) provides that for an article of food that is a low-acid canned food, the ACE filer must transmit at the time of filing entry the FCE number, SID, and can dimensions or volume, except that the ACE filer does not need to submit this information if the LACF product is for laboratory analysis only and will not be taste tested or otherwise ingested. Because we also do not believe we will generally need this information to effectively identify acidified food products in similar circumstances, we have made similar revisions to § 1.73(c). Specifically, we have revised § 1.73(c) to provide that for an article of food that is an acidified food, the ACE filer must submit at the time of filing entry the FCE number, SID, and can dimensions or volume, except that the ACE filer does not need to submit this information if the acidified food product is for laboratory analysis only and will not be taste tested or otherwise ingested. We consider LACF and acidified food products to be for laboratory analysis only and not taste tested or otherwise ingested only if the entire article will be used completely in the laboratory analysis, destroyed by the laboratory analysis, or destroyed following a reasonable retention period after the laboratory analysis. No portions of the article can be taste tested or otherwise consumed by humans or animals. Consequently, if an LACF or acidified food product being imported or offered for import will be used for product promotional tasting or other types of research in which the food will be ingested, ACE filers are required to submit the FCE number, SID, and can dimensions or volume information in ACE at the time of entry. In order to allow ACE filers to identify in ACE any LACF or acidified foods that are for laboratory analysis which do not require submission of the FCE number, SID, and can dimension or volume, we intend to create an FDA product code that can be used to identify such foods. When ACE filers use this product code, they will not be required to submit the FCE number, SID, and can dimension or volume information in ACE at the time of entry. ACE filers should be aware that entries submitted in ACE that include this new product code will be subject to manual review for an admissibility determination by FDA.

6. Human Drugs

Drug registration number. We proposed to require the submission of the Drug Registration Number in ACE at the time of entry. For purposes of this rule, the Drug Registration Number that would be submitted in ACE is the

unique facility identifier (UFI) of the foreign establishment where the drug was manufactured, prepared, propagated, compounded, or processed before being imported or offered for import into the United States.

(Comment 15) One commenter requested clarification regarding what number was required to be submitted for the Drug Registration Number.

(Response 15) We published a final rule on August 31, 2016, regarding the requirements for Drug Registration and Listing (81 FR 60170). FDA also provides guidance and instruction on establishment registration on our Web site (see, *e.g., http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm*)

7. Animal Drugs

One comment supported inclusion of all of the proposed data elements to be submitted in ACE for importation of animal drugs, noting that all clearly impact admissibility. We are finalizing these provisions without change.

8. Medical Devices

a. *Registration and Listing.* We proposed to require that the applicable Registration and Listing Numbers of the Domestic Manufacturer, Foreign Manufacturer, and/or Foreign Exporter for each medical device identified in the entry, be submitted in ACE at the time of entry.

(Comment 16) One commenter stated that if there are different medical device registrants involved in the same entry, for example a foreign manufacturer and a foreign exporter, only one medical device registration and listing number should be required and this would be sufficient for FDA to make an admissibility decision.

(Response 16) As explained in the preamble of the proposed rule, we have determined that the registration numbers of certain parties involved in the importation of a medical device (as well as the device listing number) may be material to our admissibility review. Submission of one party's registration number does not convey the registration information for another party involved in the importation of a medical device. Device foreign exporters can and do vary for medical devices manufactured at a particular firm and thus the information for all parties involved is needed at the time of entry. In addition, the time needed for an FDA reviewer to attempt to ascertain that information from our records or to request that information from the ACE filer or importer during a manual review can result in a lengthy delay in our admissibility determination. As such, we are not amending this requirement.

b. *Device listing number.* We proposed to require that the Device Listing Number (LST) required under section 510 of the FD&C Act (21 U.S.C. 360) and part 807 (21 CFR part 807) for each medical device identified in the entry, be submitted in ACE at the time of entry. Providing the LST will allow FDA to review important information during our initial admissibility review as the information for each listed medical device, as enumerated in § 807.25(g), includes the proprietary or brand name(s) under which each medical device is marketed and the activities or processes that are conducted on or done to the medical device at each establishment (*e.g.,* manufacturing, repacking, relabeling, developing specifications, remanufacturing, single-use device reprocessing, contract manufacturing, or contract sterilizing). When the listing process is complete, FDA issues an LST for each medical device associated with a particular registration.

(Comment 17) Some commenters, while recognizing that the LST is a critical component of our admissibility review, felt that the LST should be made publicly available by FDA to ensure that ACE filers have this information to submit in ACE at the time of entry. The commenters asserted that, if LSTs are not publicly available (and thus potentially not readily available to ACE filers), this will cause unnecessary disruptions and additional caged shipments. They suggest that an alternative to making the LST publicly available is to continue to allow ''UNK'' to be submitted for the LST.

(Response 17) We do not agree that FDA should make LSTs publicly available, and decline to make the requested revisions to the requirement to submit the LST (*i.e.,* permit the use of ''UNK'' instead of the LST).

As explained in the preamble to the proposed rule, in the device registration and listing process, FDA issues a registration number to the registrant that is publicly available and an LST for each device associated with the registration. Under section 510(f) of the FD&C Act, device listing information ''shall be exempt from such inspection unless the Secretary finds that such an exemption would be inconsistent with protection of the public health.'' Under § 807.37(b)(2), FDA-assigned LSTs are expressly excluded from public inspection or posting on the FDA Web site. In the **Federal Register**, FDA provided the following brief explanation for that exclusion: ''Listing numbers serve important governmental functions that may be harmed if they were made public'' (77 FR 45927 at 45930 (Aug. 2, 2012)).

The confidentiality of LSTs serves important public health interests and helps to prevent the importation of substandard, mislabeled, and counterfeit medical devices. Some imports, *e.g.,* counterfeit devices, may not be as safe and effective as devices approved or cleared for the U.S. market, may have been inadequately stored or maintained according to standards applicable outside the United States, or may be labeled or bear inadequate instructions for use in foreign markets. All of these issues can impact patient safety. FDA, therefore, will not be making LSTs publicly available as requested by commenters. Moreover, FDA will not be allowing ''UNK'' to be entered for LST as doing so would also increase the likelihood that counterfeit devices could enter the U.S. market and harm consumers. Although ''UNK'' cannot be used in lieu of an LST, ''UNK'' is an option for the intended use code.

ACE filers and importers in an established transactional or commercial relationship with the registrant will have access to the proprietary LST to submit in ACE at the time of entry.

c. *Investigational devices.* We proposed to require that an ACE filer submit in ACE at the time of entry, in the data field for the investigational device exemption (IDE) number in ACE, for an investigational device that is being imported or offered for import: (1) The IDE number for a medical device granted an exemption under section 520(g) of the FD&C Act (21 U.S.C. 360j(g)) or (2) ''NSR'' for a medical device to be used in a nonsignificant risk or in an exempt study (§ 1.76(b)).

One comment supportive of this provision in the proposed rule was received and we are finalizing this provision without change.

d. *Impact resistant lens.* We proposed to require for impact resistant lenses in eyeglasses and sunglasses an Affirmation of Compliance with the applicable requirements of § 801.410 (21 CFR 801.410) at the time of entry in ACE. This regulation states that importers may have the tests required by § 801.410(d) conducted in the country of origin but they must make the results of the testing available, upon request, to FDA, as soon as practicable (§ 801.410(g)). The current Affirmation of Compliance Code is ''IRC.''

(Comment 18) Two commenters requested that FDA clarify whether impact-resistant lenses imported for personal use require submission of the IRC Affirmation of Compliance Code at

the time of entry in ACE and whether an ACE filer must possess or submit the results of the ''drop fall'' test under § 801.410 in order to submit that Affirmation of Compliance when applicable.

(Response 18) For further relevant information on the importation of impact-resistant lenses for personal use, please see FDA's Supplemental Guide to the CATAIR (available at *https://www.cbp.gov/document/guidance/fda-supplemental-guide-release-16*), Chapter 9 of FDA's Regulatory Procedures Manual (available at *http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074300.pdf*), and FDA's Impact-Resistant Lenses: Questions and Answers Guidance (available at *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070755.pdf*).

As in the past, an ACE filer submitting ''IRC'' in ACE at the time of entry may rely on a drop-fall test certificate from the manufacturer or from a third party confirming to the ACE filer that the import satisfies the applicable requirements of § 801.410.

e. *Investigational new drug application number.* Proposed § 1.76(h), as explained in section V.C.5.h of the preamble of the Proposed Rule, would require the ACE filer, in the case of a combination product consisting of at least one medical device and one drug intended for human use and subject to an investigational new drug application (IND), to submit in ACE at the time of entry the IND number if FDA has designated the Center for Devices and Radiological Health (CDRH) as the center with primary jurisdiction for the premarket review and regulation of the combination product.

(Comment 19) We received a comment asserting that a combination product consisting of at least one medical device and one investigational new drug where FDAs CDRH has been designated as the center with primary jurisdiction would rightfully be conducted under an IDE rather than an IND. The commenter expressed the opinion that the final rule should distinguish between a combination product approved under an IDE and a combination product approved under an IND.

The commenter also observed that the proposed rule only addressed the importation of stand-alone medical devices not associated with a combination product and not the importation of devices that are included in combination products. Although medical device components of combination products may be integrated directly with a drug or biologic (21 CFR 3.2(e)(1)) or co-packaged with a drug or biologic (21 CFR 3.2(e)(2)), the commenter stated, the proposed rule did not appear to discuss the importation of medical device components of drug- or biologic-primary mode of action combination products regulated by CDER or CBER and approved for marketing under a new drug application or a biologics license application.

(Response 19) In light of this comment and based on further FDA review, FDA is not finalizing proposed § 1.76(h). FDA believes that the other requirements in §§ 1.74, 1.76, and 1.78 of the final rule, regarding products subject to the various types of applications, including investigational use applications, will suffice for combination products. If warranted, FDA will provide additional information on submitting this information for imported combination products in future guidance or other published materials.

f. *Convenience kit.* We proposed to require that a medical device that is a convenience kit or part of a convenience kit and is a re-import of a medical device manufactured in the United States or is an import of a medical device manufactured outside the United States be identified as such in ACE at the time of entry using the current Affirmation of Compliance Code ''KIT.''

(Comment 20) One commenter was not sure that this data element will aid FDA in making admissibility decisions.

(Response 20) The purpose of the convenience kit data element is to facilitate our admissibility review of medical device products approved or cleared for marketing as a kit by FDA, and to identify convenience kits that include recalled or unapproved medical devices. As explained in the preamble to the proposed rule, convenience kits imported or offered for import have been found at times to contain recalled or unapproved medical devices.

9. Radiation-Emitting Electronic Products

We received no comments regarding this proposed provision, and we are finalizing it without change.

10. Biological Products, HCT/Ps, and Related Drugs and Medical Devices

HCT/P Registration Number and Affirmation of Compliance. Human cells, tissues, or cellular or tissue-based products are articles containing or consisting of human cells or tissues intended for implantation, transplantation, infusion or transfer into a human recipient (§ 1271.3(d)). For HCT/Ps manufactured by establishments required to register under part 1271 and regulated solely under section 361 of the PHS Act and the regulations in part 1271, we proposed to require the submission of that registration number in ACE at the time of entry. The current Affirmation of Compliance Code for the HCT/P Registration Number is ''HRN''.

We also proposed to require for HCT/Ps regulated solely under section 361 of the PHS Act and the regulations in part 1271 being imported or offered for import that are not otherwise exempt, that an Affirmation of Compliance with all applicable requirements of part 1271 be submitted in ACE at the time of entry. The current Affirmation of Compliance Code for HCT/Ps to affirm compliance with part 1271 is ''HCT''.

(Comment 21) One comment agreed with most of the proposed requirements specific to biological products, HCT/Ps, and related drugs and medical devices, because the data clearly impacts admissibility. However, the comment questioned the need for the submission of HCT/P registration number and Affirmation of Compliance, and expressed a belief that this information is not applicable to admissibility.

(Response 21) We acknowledge and appreciate the supportive comments. We disagree that the HCT/P registration number and Affirmation of Compliance are not applicable to our admissibility review. As noted in the proposed rule, establishments that manufacture HCT/Ps are required to register and list their HCT/Ps in accordance with part 1271, subpart B, unless they are subject to an exception under 21 CFR 1271.15. When an establishment successfully completes the required registration process, CBER assigns a unique registration number to that firm. FDA established these registration requirements, as well as other requirements in part 1271 (*e.g.,* donor eligibility and current good tissue practice requirements) to prevent the introduction, transmission, or spread of communicable diseases by HCT/Ps. Requiring submission of the HCT/P registration number and Affirmation of Compliance helps to ensure compliance with the part 1271 requirements and is necessary to prevent the introduction, transmission, or spread of communicable diseases by HCT/Ps. Accordingly, we have finalized these requirements as proposed.

11. Tobacco Products

a. *Brand name.* We proposed to require that the brand name for a tobacco product be submitted in ACE at the time of entry.

(Comment 22) Several comments expressed concern that not all tobacco products have brand names.

(Response 22) FDA recognizes that not all tobacco products have specific brand names. One key example is tobacco products for further manufacturing; another example is rolling papers that may not have a specific brand name, and only bear the manufacturer name. Thus, the final rule allows the ACE filer to submit the commercial name for the brand name in ACE if the product is unbranded. Further, in the final rule, this data element does not apply to products solely intended for further manufacturing or to investigational tobacco products.

We note that, for purposes of this rule, brand name includes brand and sub-brand, for example: ''Acme Silver Box 100s,'' or ''Acme Little Cigars.''

b. *Name and address of the ACE filer.* We proposed to require that the name and address of the ACE filer for import entries that include a tobacco product be submitted in ACE at the time of entry. We invited comments on the advantages, disadvantages, and feasibility of requiring an ACE filer to submit this information in ACE at the time of entry. In particular, we invited comment on whether the submission by an ACE filer of the name and address of the ACE filer for import entries that include a tobacco product would help us achieve our goals of facilitating admissibility review and focusing our resources on those products that may be associated with a serious public health risk to consumers and whether this could be sufficiently accomplished through proposed § 1.72(b) or other means.

We received a number of comments in opposition to this provision and after consideration of those comments we have decided not to finalize this provision.

12. Cosmetics

We received no comment regarding proposed § 1.80, other than the comments regarding § 1.72 which are addressed previously in this document. Under proposed § 1.80, we proposed to require that an ACE filer must submit the data specified in § 1.72 at the time of filing entry in ACE. We are finalizing this provision without change.

13. Technical Amendments in the Proposed Rule

a. *Revisions to §§ 1.83 and 1005.2.* We proposed to revise §§ 1.83 and 1005.2 to update the legal references in those sections in order to bring the definition of ''owner and consignee'' in section 801 of the FD&C Act back in line with the customs terminology and to make clear that ''owner or consignee'' continues to mean the person authorized to make entry, now designated under customs law as the ''importer of record.''

(Comment 23) Several comments stated that redefining ''owner or consignee'' in § 1.83 as ''the person eligible to make entry'' under the relevant provisions of the Tariff Act of 1930 was confusing because several persons are in fact eligible to become the ''importer of record'' and therefore to make entry. The commenters suggested that FDA define ''owner or consignee'' as the ''person who makes entry.''

(Response 23) We agree and have revised the final rule to provide that the ''owner or consignee'' is defined as the ''person who makes entry'' under section 484 of the Tariff Act of 1930 (19 U.S.C. 1484). We removed the reference to section 485 of the Tariff Act of 1930 and 19 U.S.C. 1485 as that section relates to the filing of a declaration by the importer of record. We made the same change to § 1005.2.

(Comment 24) One commenter suggested that we should adopt a definition of ''owner or consignee'' that is more consistent with the definition of ''importer'' adopted by FDA in other areas, for example, in our proposed rule on Foreign Supplier Verification Programs (FSVP).

(Response 24) We decline to revise the rule as suggested in this comment. FDA adopted a definition of ''importer'' (§ 1.500) in our final FSVP rule published on November 27, 2015, that best serves the specific purposes of the FSVP requirements for importers of food for humans and animals, consistent with the statutory provisions the FSVP regulation must implement (80 FR 74226 at 74239). The purpose of the technical amendments to 21 CFR 1.83 and 1005.2 is to update the definition of ''owner or consignee'' to take into account revisions to the provisions of the Tariff Act of 1930 that were referenced in those regulations. Since the relevant person for these purposes is the ''importer of record,'' FDA is defining ''owner or consignee'' as the ''importer of record'' as that term is used in the Tariff Act of 1930.

b. *Electronic notification in §§ 1.90 and 1.94.* We proposed to revise § 1.90 to allow FDA to provide notice of sampling directly rather than through the ''collector of customs'' which will normally happen through a secure electronic system. We also proposed to revise § 1.94 to clarify that FDA can provide either written or electronic notification to an owner or consignee when FDA has determined that an article being imported or offered for import may be subject to refusal of admission and/or administrative destruction.

(Comment 25) One commenter requested clarification regarding whether electronic notification will completely replace written or facsimile communication for these purposes.

(Response 25) While our intent is to move to an automated, electronic process to expedite the notification process for both the Agency and the trade, FDA will still consider providing a written or facsimile notification if, under the circumstances, that is the most efficient and effective means to provide any such notification.

(Comment 26) Several commenters supported FDA providing electronic notification of FDA actions but also requested that, in addition to providing notification to the owner or consignee, FDA provide electronic notification to other parties to the import.

(Response 26) We decline to require that the Agency provide electronic notification under § 1.94 to a person other than the owner or consignee which, pursuant to the revision to § 1.83 in the final rule, is the importer of record. The purpose of § 1.94 is to provide the importer of record of an FDA-regulated article being imported or offered for import into the United States with notice and opportunity to present testimony to the Agency prior to refusal of admission of an FDA-regulated article or prior to administrative destruction of certain refused drugs. There is only one importer of record and only that person has the right to notification and a hearing under § 1.94.

14. Effective Date

FDA proposed that the effective date of the final rule would be 30 days after its publication in the **Federal Register**.

(Comment 27) FDA received comments expressing concern about an effective date of 30 days after publication of the final rule, stating that this does not provide enough time for the necessary programming integration between ACE, FDA's OASIS system, the ACE filers' and the importers' systems. One comment suggested that the trade industry will resort to manual data entry while the data feeds are being developed. The comments suggested effective dates that ranged from 60 days to 180 days after publication of the final rule. One comment suggested that FDA adopt a gradual and incremental approach to requiring submission of the data elements in the final rule.

(Response 27) We decline to change the effective date of the final rule. As of July 23, 2016, ACE became the sole CBP-authorized EDI system for electronic entry and entry summary filings for importation of FDA-regulated products. The trade community has already transitioned to ACE and software is available in the marketplace that conforms with the requirements in FDA's Supplemental Guide to the CATAIR. FDA acknowledges that software vendors and the trade community may need to make a small number of alterations to their current programming to be consistent with the requirements in the final rule but 30 days should be sufficient for that purpose. FDA will shortly issue an updated FDA Supplemental Guide to assist software vendors and the trade industry with their programming needs.

15. Summary of Benefits and Costs

(Comment 28) Several commenters emphasized that each additional data element that will be mandated by this FDA rulemaking represents real cost added to the entry process.

(Response 28) We understand that each additional data element that firms will be required to submit in ACE at the time of entry represents added cost to the entry process. FDA has removed some of data elements from the final rule, which should lessen the burden.

While FDA is requiring ACE filers to submit more data upfront, we believe that this may not necessarily end up being burdensome to the industry over time. The Agency believes that, after the initial adjustment stage, submission of the required data will result in faster processing time and cost savings to the industry and FDA.

(Comment 29) Some commenters opined that FDA underestimated transition costs.

(Response 29) In the Preliminary Regulatory Impact Analysis (PRIA) we recognized the uncertainty surrounding our cost estimates for scenario 1, including transition cost estimates in the first year. We requested comments to provide additional data and information to improve these cost estimates. We did not receive any additional information that would help improve our transition cost estimates.

(Comment 30) Several commenters complained that the PGA message set in ACE often experiences system outages, failures to perform necessary functions, and that the time that FDA takes to process entries has already doubled for some ACE filers. They assert that this causes ''down time'' and significant added costs to the trade industry.

(Response 30) System outages and failures to perform necessary functions should be in part attributed to ACE implementation by CBP. In order to address these comments and also Comment 27 about alleging underestimated transition costs, we have revised our ranges for first year estimates and doubled the time necessary for filing entries in ACE for FDA-regulated products during the initial adjustment period.

(Comment 31) Some commenters said that FDA dismissed additional costs of reprogramming caused by further changes to the CATAIR.

(Response 31) In the PRIA (page 22), we stated that because the costs of updating the existing software or purchasing a new one would fall under the cost of CBP action of implementing ACE, we do not include these transition costs in our economic impact analysis. FDA expects that software updates occur regularly as a part of ongoing business practice and the price of new off-the-shelf software would incorporate all ACE requirements, including FDA PGA message set requirements. The commenters did not provide any new information that can be used to estimate the share of reprogramming costs that should be attributed only to FDA rulemaking and not the entire CBP action of implementing ACE.

(Comment 32) One commenter stated that only importers with large budgets can generate, maintain, and provide data electronically.

(Response 32) FDA acknowledges this viewpoint, but because most importers including small businesses typically hire customs brokers to electronically file entries for them in ACE, FDA expects that reprogramming costs would fall on customs brokers as a part of costs of doing business related to imports. As stated previously, approximately 98 percent of importers use customs brokers to file their entries of FDA-regulated products impacted by the final rule.

(Comment 33) Some commenters stated that the cost to file FDA entries in ACE increased by 8 minutes (by over 50 percent) and that 40 percent more staffing is required because, compared to ACS, FDA data requirements are different in ACE.

(Response 33) We incorporated this new information from the industry into our ranges of cost and time estimates for the final rule. That being said, the 50 percent time increase to process an FDA entry in ACE and the estimated 40 percent labor cost increase asserted by commenters could be caused by: (1) The overall switch from ACS to ACE (which should be attributed to the cost of ACE implementation by CBP) and (2) the additional time required for filing FDA data elements that are required in the final rule (which should be attributed to the cost of the FDA rulemaking; that is unless a filer already voluntarily provided these data elements to FDA in ACS on a regular basis). Only the costs caused by (2) should be attributed to FDA rulemaking (see scenario 1 in the PRIA).

Furthermore, it is not clear from the comment whether the 50 percent time increase and the 40 percent staffing cost increase are the same across the entire industry. In the PRIA, FDA estimated that for each FDA-regulated unique product-manufacturer import line, it would take up to 8 additional minutes to prepare and look up information mandated by the proposed rule and up to 4 additional minutes (5 minutes in the first year) to file that information in ACE, for a total of up to 12 minutes per unique import line (up to 13 minutes in the first year). Therefore, an 8 minute increase (= 24 minutes minus 16 minutes) per import line described by these comments is a possible outcome, especially in the initial adjustment stage, that is consistent with our analysis in the PRIA.

D. Technical Amendments in the Final Rule

We made three technical changes to the proposed rule due to our issuance of a final rule on August 31, 2016, regarding the requirements for drug registration and listing (81 FR 60170) that was published after our Notice of Proposed Rulemaking for this rule (published on July 1, 2016 (81 FR 43155)).

Under §§ 1.74(a), 1.75(a) and 1.78(d) of our proposed rule, an ACE filer would be required to submit the Drug Registration Number and Drug Listing Number in ACE at the time of entry for an article which is a drug if it is from a foreign establishment where the drug was manufactured, prepared, propagated, compounded, or processed before being imported or offered for import into the United States that is required to be registered and the drug to be listed under section 510 of the FD&C Act. The final drug registration and listing rule amended 21 CFR parts 207 and 607 which provide the regulatory requirements for drug registration and listing including who must register their establishments and list their drugs annually with the FDA.

In this final rule, we have not changed the requirement that ACE filers submit a Drug Registration Number and a Drug Listing Number in ACE at the time of entry except that, as discussed earlier in

this document, we have removed the requirement for submission of a drug listing number from § 1.78(d) for CBER-regulated drugs. For purposes of clarity regarding the underlying requirement of who must register and list their drugs with FDA, we have added a reference to part 207 in § 1.74(a) for human drugs, § 1.75(a) for animal drugs, and § 1.78(d) for those drugs regulated by CBER. Because the drugs regulated by CBER include blood and blood products we have also added a reference in § 1.78(d) to part 607, which contains the registration and listing requirements for blood and blood products.

VI. Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. We believe that this final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. By requiring import entry filers to submit data elements mandated by this final rule into ACE and updating certain sections of 21 CFR Chapter I, we intend to streamline our import entry admissibility review and reduce ambiguity about the import process. Small businesses will be affected by this final rule in the same way as non-small businesses. Because the burden of switching from ACS to ACE is already covered by CBP's ACE regulation, for those small business filers that choose to continue filing electronically (and, therefore, must use ACE), we believe that providing several additional data elements to FDA via ACE in exchange for a more streamlined process and potentially receiving an import admissibility decision faster would not cause a significant impact. These small businesses would bear the costs of this rule, but would also enjoy most of the benefits. We therefore certify that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $146 million, using the most current (2015) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Benefits and Costs of the Final Rule

FDA is issuing a final rule to establish requirements for the electronic filing of import entries in ACE. The final rule will require that certain data elements material to our admissibility review be submitted to the FDA via ACE as part of an electronic import entry. This final regulation will help streamline FDA's existing admissibility procedures for FDA-regulated commodities imported or offered for import into the United States. For import entries submitted electronically, FDA will require that certain key data be submitted as a part of the import entry filing in ACE. The final regulation also provides further clarifications to the import process by revising sections of 21 CFR Chapter I relating to the definition of owner or consignee; the notice of sampling; and notices of FDA actions related to FDA-regulated products being imported or offered for import into the United States, such as notices of hearing on refusal of admission or administrative destruction, to allow for electronic notification by FDA. The rule also clarifies that importers of record of human cells, tissues, or cellular or tissue-based products (HCT/Ps) that are regulated solely under section 361 of the PHS Act and part 1271, unless exempted, will be required to submit the applicable data elements included in the final rule in ACE at the time of entry.

The estimated costs of the final rule—and the cost savings—stem from the mandatory information that will be submitted and collected under the ACE system. In the baseline scenario for our estimates of these costs, we assumed that without this final regulation the information would be collected by ACE only if and to the extent that it is voluntarily provided by filers like under the former ACS system (table 2). Annualized over a 20-year horizon, the costs of complying with this final regulation are between $27.7 million and $69.1 million per year with a 3 percent discount rate; these costs are between $26.8 million and $66.7 million per year with a 7 percent discount rate (table 2). The total annualized cost savings to the entire society cannot be fully quantified because of the lack of certain data currently available to the Agency. Partially quantifiable cost savings are estimated to range from $2.6 million to $43.4 million with a 3 percent discount rate; these partially quantifiable benefits are estimated to range from $2.6 million to $43.4 million with a 7 percent discount rate (table 2). These benefits, in terms of cost savings, to both FDA and the industry that we are able to quantify will arise from FDA simplifying the notification process on certain FDA actions taken by the Agency under section 801 of the FD&C Act by allowing electronic notification of the owner or consignee.

Cost savings to both the industry and FDA that we are unable to quantify will potentially arise from the reduced time of import entry processing and fewer imported products being held, and a shorter timeframe between the time of entry submission and a final admissibility decision by FDA as a result of increased efficiency in FDA's imports admissibility process. Other potential benefits of this final rule that we are unable to quantify will result from compliant FDA-regulated imports reaching U.S. consumers faster and a reduction in the number of non-compliant imports reaching U.S. consumers, thereby making the overall supply of FDA-regulated products on the U.S. market safer. Other potential benefits in the form of cost savings that we are similarly unable to quantify will arise because by revising certain sections of 21 CFR Chapter I the Agency would provide more clarity to the industry about certain aspects of the overall process of import admissibility for FDA-regulated products.

TABLE 2—TOTAL ANNUALIZED COSTS AND BENEFITS OF THE FINAL RULE [1]

Discount rate (percent)	Total annualized costs	Total benefits	
		Cost savings	Other benefits (not quantified)
3	$46.7 million (range $27.7 million to $69.1 million).	$21.0 million (range $2.6 to $43.4 million).	Potential time reduction for processing import entry declarations by FDA; potential increase in predictability of the import process; potentially shorter timeframes for imported products being held pending a final admissibility decision; more efficient use of FDA's internal resources; potentially fewer recalls of imported products; reduction of counterfeit and misbranded imports on the U.S. market; increased efficiency of the overall import process due to decreased ambiguity because of a better defined *the owner or consignee* term, the clarifications related to notice of sampling, and allowing for electronic notice of certain FDA actions related to hearing on refusal of admission of imports and destruction of drugs.
7	$45.1 million (range $26.8 million to $66.7 million).	$21.0 million (range $2.6 million to $43.4 million).	Potential time reduction for processing import entry declarations by FDA; potential increase in predictability of the import process; potentially shorter timeframes for imported products being held pending a final admissibility decision; more efficient use of FDA's internal resources; potentially fewer recalls of imported products; reduction of counterfeit and misbranded imports on the U.S. market; increased efficiency of the overall import process due to decreased ambiguity because of a better defined *the owner or consignee* term, the clarifications related to notice of sampling, and allowing for electronic notice of certain FDA actions related to hearing on refusal of admission of imports and destruction of drugs.

[1] We generated upper and lower bounds using Monte Carlo simulations.

The Economic Analysis of Impacts of the final rule performed in accordance with Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act, and the Unfunded Mandates Reform Act of 1995 is available to the public in the docket for this final rule (Docket No. FDA–2016–N–1487) at *https://www.regulations.gov* and is also available on FDA's Web site at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm* (Ref. 1).

VII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown in the following paragraphs with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering the data needed, and completing and reviewing each collection of information.

Title: Importer's Entry Notice.

Description: We are issuing a regulation that requires ACE filers to submit certain information in ACE or any other CBP-authorized EDI system related to FDA-regulated products they are importing or offering for import into the United States. The information collection provisions of the rule, specifically the amendment of 21 CFR part 1 by adding §§ 1.70 through 1.81, will allow us to require ACE filers to submit in ACE at the time of entry important and useful information about FDA-regulated products being imported or offered for import into the United States, beyond the information that was submitted previously. The information collection provisions of this rule will facilitate an effective and efficient admissibility review of FDA-regulated products being imported or offered for import into the United States, and protect public health by allowing us to focus our limited resources on those FDA-regulated products being imported or offered for import that may be associated with a greater public health risk.

The authority to issue this regulation and to conduct the associated information collection is found in sections 801, 701, and 536 of the FD&C Act, sections 351, 361, and 368 of the PHS Act, and section 713 of FDASIA (which added section 801(r) to the FD&C Act).

To account for the information collection provisions of the rule, we are amending the information collection currently approved under OMB control number 0910–0046. The information collection approved under OMB control number 0910–0046 has historically accounted for the collection of information from entry filers for FDA-regulated products being imported or offered for import into the United States. The vast majority of this information was submitted by entry filers electronically in ACS. On July 23, 2016, ACE replaced ACS as the sole EDI system authorized by CBP for submission of electronic entry and entry summary information for FDA-regulated products being imported, or offered for import, into the United States. Although much of the information collection pursuant to this rule was previously collected from entry filers for FDA-regulated products being imported or offered for import into the United States, and was approved for collection under OMB control number 0910–0046, this rule requires ACE filers to submit certain information in addition to what entry filers were previously submitting.

The annual recordkeeping requirements for this collection are accounted for by the ''Customs Modernization Act Recordkeeping Requirements'' information collection approved by OMB under OMB control number 1651–0076.

Of note, in addition to accounting for the information collection pursuant to

the rule, we are also adjusting the existing estimated burden approved under OMB control number 0910–0046 upwards to account for an increase in FDA-regulated import lines, to account for the submission of intended use information, which had previously been submitted by entry filers but not accounted for under an approved FDA information collection, and to correct for our previous underestimates of the number of FDA-regulated entries. Accordingly, we are adjusting upward the estimated existing burden under OMB control number 0910–0046 (without yet accounting for the information collection of the rule) to 1,186,464 hours.

The information collection provisions of this rule are in §§ 1.72, 1.73, 1.74, 1.75, 1.76, 1.77, 1.78, 1.79, and 1.80. Section 1.72 requires certain product identifying data elements and certain entity identifying data elements to be submitted in ACE at the time of entry for food contact substances, drugs, biological products, HCT/Ps, medical devices, radiation-emitting electronic products, cosmetics, and tobacco products. Sections 1.73 through 1.80 require certain data elements to be submitted in ACE depending on the type of FDA-regulated article being imported or offered for import into the United States. Sections 1.73, 1.74, 1.75, 1.76, 1.77, 1.78, 1.79, and 1.80 apply, respectively, to certain food products (food contact substances, low-acid canned food, and acidified food); human drugs; animal drugs; medical devices; radiation-emitting electronic products; biological products, HCT/Ps, and related drugs and medical devices regulated by CBER; tobacco products; and cosmetics.

Although we did not receive any comments specifically relating to the information collection burden pursuant to the information collection provisions of the rule, we did receive comments relating to the rule and the Regulatory Impact Analysis (RIA). We have revised our information collection burden estimates as appropriate to reflect those revisions we made to the rule and the RIA.

Description of Respondents: The primary respondents to this collection of information are domestic and foreign importers of FDA-regulated articles being imported or offered for import into the United States and ACE filers. An importer of record may be the owner or purchaser of the article being imported or offered for import, or a customs broker licensed by CBP under 19 U.S.C. 1641 who has been designated by the owner, purchaser, or consignee to file the import entry. There is only one importer of record per entry.

Using the estimates in the RIA for the rule, we estimate there are about 41,703 owners or purchasers of FDA-regulated commodities who seek to import FDA-regulated articles (''importers'') into the United States on an annual basis. We have estimated that 97.7 percent of these importers will use customs brokers to file their import entries in ACE, and the other 2.3 percent will file their import entries themselves. We thereby estimate that there are a total of 3,667 entry filers, which includes the 959 owners or purchasers of the article who will file their own import entry in ACE (= 41,703 importers × (100 − 97.7) percent).

Reporting Burden: We have used the relevant assumptions and estimates in Option 1 of the RIA for this rule to estimate the annual information collection burden pursuant to the rule. Option 1 of the RIA is the option which reflects the rule.

Of the data elements that the rule requires ACE filers to submit in ACE at the time of entry, all except for four, were previously collected from entry filers (as either required or optional submissions, depending on the data element) and have been accounted for by the previously approved information collection under OMB control number 0910–0046. One of those four data elements, intended use information, had been collected from entry filers but not accounted for under an OMB approved information collection. Under the rule, intended use information is collected in ACE in the form of an IUC, instead of in the form of a text input into the CBP-required product description field, as it had been collected previously in ACS. The rule provides for the collection of three data elements to be collected in ACE that are new, *i.e.,* we have not previously collected the information from entry filers. One of the three new data elements is required by § 1.72 which applies to food contact substances, drugs, biological products, HCT/Ps, medical devices, radiation-emitting electronic products, cosmetics, and tobacco products, and is the telephone and email address for the importer of record, which will help to facilitate electronic notices provided by FDA under § 1.94 for certain FDA actions. One of the other two new data elements is required by § 1.78, which applies only to biological products, HCT/Ps, and related drugs and medical devices, and is the product name, and the other is required by § 1.79, which applies only to tobacco products, and is the brand name of the tobacco product.

Although just three data elements collected pursuant to the rule are new, we expect that filers who were not submitting certain previously optional data elements in ACS that the rule now requires ACE filers to submit in ACE will begin submitting those data elements in order to comply with the rule. We expect this to be the primary cause of the increased reporting burden pursuant to the rule. Notably, however, the submission rates of many of these data elements in ACS were quite high, although their submission varied by commodity. For example, in 2015 approximately 98 percent of medical device lines were submitted in ACS with at least one Affirmation of Compliance. Based on 2014 and 2015 data, we estimate that medical device lines will make up approximately seventy percent of all import lines that will be impacted by the rule. On the other hand, for example, in 2015 only 24 percent of animal drug import lines were submitted in ACS with at least one Affirmation of Compliance, although, based on 2014 and 2015 data, we estimate that animal drugs will make up less than 0.5 percent of all import lines that will be affected by the rule.

Using the estimates in the RIA for the rule, we have estimated that the rule will impact 23,119,465 import lines in the first year. The rule will not impact import lines of foods other than acidified foods, low-acid canned foods, and food contact substances. We have also estimated that 504,768 of affected import lines in the first year represent unique product-manufacturer combinations. We have estimated that the number of impacted import lines will grow at an average rate of about 3.3 percent per year. For the purposes of calculating the additional annual recurring reporting burden of the rule, we have annualized those 3.3 percent per year increases for 3 years.

Other key assumptions in the RIA (Option 1) for the rule that affect our estimate of the additional annual reporting burden are:

- Respondents (ACE filers) will have to become aware of the rule's requirements, which will include activities related to reading the rule, understanding the reporting requirements, consulting with specialists if necessary, determining how to best meet these requirements, and communicating these requirements to workers; and this is a one-time event that will require an average of 30 minutes.
- Respondents (owners or purchasers) will require an administrative worker to locate, gather, and prepare the additional information required by this

rule for each unique product-manufacturer import line; and this will require on average about 2.333 minutes (0.03889 hours) per line.

- Respondents (ACE filers) will require an administrative worker to submit the applicable data elements required in the final rule and Respondents (ACE filers) may also require an owner or manager to check if the information is correct, or alternatively, the administrative worker to quality check their submission using software that is connected to ACE and this will require about 1.166667 minutes (approximately 0.01944 hours) per line on average.
- It will take respondents about 25 percent more time in the first year for an administrative worker to complete each import line and quality check the information, because the respondent will have to adjust to the new system and data elements.

We expect the annual recurring reporting burden for the information collection pursuant to this rule to be as follows:

TABLE 3—ESTIMATED ADDITIONAL ANNUAL RECURRING REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Preparing the required information (applies to unique lines only).	41,703	12.5	521,609	0.03889 (2.333 minutes).	20,285
Quality checks and data submission into ACE	3,667	6,515	23,890,800	0.01944 (1.1667 minutes).	464,543
Total					484,828

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We expect the additional one-time (*i.e.,* occurring only in the first year) reporting burden for the information collection that will result from this rule to be as follows:

TABLE 4—ESTIMATED ONE TIME REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Review and familiarization with the rule	3,667	1	3,667	0.5 (30 minutes)	1,834
First year adjusting to new requirements that will result in an average of 25 percent more time for quality checks and submission into ACE.	3,667	6,305	23,119,465	0.00486 (0.29 minutes).	112,386
Total					114,220

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Accordingly, we estimate that the additional annual reporting burden under the rule will be 599,048 hours in the first year (484,828 recurring hours + 114,220 one-time hours) and 484,828 hours recurring after the first year.

Pursuant to our revision of the information collection under OMB control number 0910–0046, which includes adjustment of the existing burden and amendment to account for the information collection provisions of the rule, the total reporting burden is 1,785,712 hours in the first year (= 1,186,464 adjusted existing burden hours + 484,828 recurring hours pursuant to the rule + 114,220 one-time hours pursuant to the rule) and 1,671,292 hours annually after the first year (= 1,186,464 adjusted existing burden hours + 484,828 recurring hours pursuant to the rule).

The information collection provisions in this final rule have been submitted to OMB for review as required by section 3507(d) of the Paperwork Reduction Act of 1995. FDA will publish a subsequent notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

IX. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. We have determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

X. Reference

The following reference is on display in the Division of Dockets Management (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at *https://www.regulations.gov.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. Final Regulatory Impact Analysis, Final Regulatory Flexibility Analysis, and Final Unfunded Mandates Reform Act Analysis for Submission of Food and Drug Administration Import Data in the Automated Commercial Environment, available at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm#*

List of Subjects

21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 1005

Administrative practice and procedure, Electronic products, Imports, Radiation protection, Surety bonds.

21 CFR Part 1271

Biologics, Drugs, Human cells and tissue-based products, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 1, 1005, and 1271 are amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

■ 1. The authority citation for part 1 is revised to read as follows:

Authority: 15 U.S.C. 1333, 1453, 1454, 1455, 4402; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 342, 343, 350c, 350d, 350e, 350j, 352, 355, 360b, 360ccc, 360ccc–1, 360ccc–2, 362, 371, 373, 374, 379j–31, 381, 382, 384a, 384b, 384d, 387, 387a, 387c, 393; 42 U.S.C. 216, 241, 243, 262, 264, 271; Public Law 107–188, 116 Stat. 594, 668–69; Public Law 111–353, 124 Stat. 3885, 3889.

■ 2. Add subpart D, consisting of §§ 1.70 through 1.81, to read as follows:

Subpart D—Electronic Import Entries

Sec.

Subpart D—Electronic Import Entries

§ 1.70 Scope.

This subpart specifies the data elements that are required by the Food and Drug Administration (FDA) to be included in an electronic import entry submitted in the Automated Commercial Environment (ACE) system or any other U.S. Customs and Border Protection (CBP)-authorized electronic data interchange (EDI) system, which contains an article that is being imported or offered for import into the United States and that is regulated by FDA.

§ 1.71 Definitions.

For purposes of subpart D:

ACE filer means the person who is authorized to submit an electronic import entry for an FDA-regulated product in the Automated Commercial Environment or any other CBP-authorized EDI system.

Acidified food means acidified food, as defined in § 114.3(b) of this chapter, and subject to the requirements in parts 108 and 114 of this chapter.

Automated Commercial Environment or *ACE* means the automated and electronic system for processing commercial importations that is operated by U.S. Customs and Border Protection in accordance with the National Customs Automation Program established in Subtitle B of Title VI—Customs Modernization, in the North American Free Trade Agreement Implementation Act (Pub. L. 103–182, 107 Stat. 2057, 2170, December 8, 1993) (Customs Modernization Act), or any other CBP-authorized EDI system.

Biological product means a biological product as defined in section 351(i)(1) of the Public Health Service Act.

Cosmetic means a cosmetic as defined in section 201(i) of the Federal Food, Drug, and Cosmetic Act.

CBP or U.S. Customs and Border Protection means the Federal Agency that is primarily responsible for maintaining the integrity of the borders and ports of entry of the United States.

Drug means those articles meeting the definition of a drug in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act.

FDA or Agency means the U.S. Food and Drug Administration.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act.

Food contact substance means any substance, as defined in section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act, that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.

HCT/Ps means human cells, tissues, or cellular or tissue-based products, as defined in § 1271.3(d) of this chapter.

Low-acid canned food means a thermally processed low-acid food (as defined in § 113.3(n) of this chapter) in a hermetically sealed container (as defined in § 113.3(j) of this chapter), and subject to the requirements in parts 108 and 113 of this chapter.

Medical device means a device as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act, that is intended for use in humans.

Radiation-emitting electronic product means an electronic product as defined in section 531 of the Federal Food, Drug, and Cosmetic Act.

Tobacco product means a tobacco product as defined in section 201(rr) of the Federal Food, Drug, and Cosmetic Act.

§ 1.72 Data elements that must be submitted in ACE for articles regulated by FDA.

General. When filing an entry in ACE, the ACE filer shall submit the following information for food contact substances, drugs, biological products, HCT/Ps, medical devices, radiation-emitting electronic products, cosmetics, and tobacco products.

(a) *Product identifying information* for the article that is being imported or offered for import. This consists of:

(1) *FDA Country of Production,* which is the country where the article was last manufactured, processed, or grown (including harvested, or collected and readied for shipment to the United States). The FDA Country of Production for an article that has undergone any manufacturing or processing is the country where that activity occurred provided that the manufacturing or processing had more than a minor, negligible, or insignificant effect on the article.

(2) *The Complete FDA Product Code,* which must be consistent with the invoice description of the product.

(3) *The Full Intended Use Code.*

(b) *Importer of record contact information,* which is the telephone and email address of the importer of record.

§ 1.73 Food.

(a) *Food contact substances.* An ACE filer must submit the information specified in § 1.72 at the time of filing entry in ACE for food that is a food contact substance.

(b) *Low-acid canned food.* For an article of food that is a low-acid canned food, the ACE filer must submit at the time of filing entry the Food Canning Establishment Number and the Submission Identifier, and can dimensions or volume, except that the ACE filer does not need to submit this information in ACE at the time of entry if the article is being imported or offered for import for laboratory analysis only and will not be taste tested or otherwise ingested.

(c) *Acidified food.* For an article of food that is an acidified food, the ACE filer must submit at the time of filing

entry the Food Canning Establishment Number and the Submission Identifier, and can dimensions or volume, except that the ACE filer does not need to submit this information in ACE at the time of entry if the article is being imported or offered for import for laboratory analysis only and will not be taste tested or otherwise ingested.

§ 1.74 Human drugs.

In addition to the data required to be submitted in § 1.72, an ACE filer must submit the following information at the time of filing entry in ACE for drugs, including biological products, intended for human use that are regulated by the FDA Center for Drug Evaluation and Research.

(a) *Registration and listing.* For a drug intended for human use, the Drug Registration Number and the Drug Listing Number if the foreign establishment where the human drug was manufactured, prepared, propagated, compounded, or processed before being imported or offered for import into the United States is required to register and list the drug under part 207 of this chapter. For the purposes of this section, the Drug Registration Number that must be submitted at the time of entry in ACE is the unique facility identifier of the foreign establishment where the human drug was manufactured, prepared, propagated, compounded, or processed before being imported or offered for import into the United States. The unique facility identifier is the identifier submitted by a registrant in accordance with the system specified under section 510(b) of the Federal Food, Drug, and Cosmetic Act. For the purposes of this section, the Drug Listing Number is the National Drug Code number of the human drug article being imported or offered for import.

(b) *Drug application number.* For a drug intended for human use that is the subject of an approved application under section 505(b) or 505(j) of the Federal Food, Drug, and Cosmetic Act, the number of the new drug application or abbreviated new drug application. For a biological product regulated by the FDA Center for Drug Evaluation and Research that is required to have an approved new drug application or an approved biologics license application, the number of the applicable application.

(c) *Investigational new drug application number.* For a drug intended for human use that is the subject of an investigational new drug application under section 505(i) of the Federal Food, Drug, and Cosmetic Act, the number of the investigational new drug application.

§ 1.75 Animal drugs.

In addition to the data required to be submitted in § 1.72, an ACE filer must submit the following information at the time of filing entry in ACE for animal drugs:

(a) *Registration and listing.* For a drug intended for animal use, the Drug Registration Number and the Drug Listing Number if the foreign establishment where the drug was manufactured, prepared, propagated, compounded, or processed before being imported or offered for import into the United States is required to register and list the drug under part 207 of this chapter. For the purposes of this section, the Drug Registration Number that must be submitted in ACE is the Unique Facility Identifier of the foreign establishment where the animal drug was manufactured, prepared, propagated, compounded, or processed before being imported or offered for import into the United States. The Unique Facility Identifier is the identifier submitted by a registrant in accordance with the system specified under section 510(b) of the Federal Food, Drug, and Cosmetic Act. For the purposes of this section, the Drug Listing Number is the National Drug Code number of the animal drug article being imported or offered for import.

(b) *New animal drug application number.* For a drug intended for animal use that is the subject of an approved application under section 512 of the Federal Food, Drug, and Cosmetic Act, the number of the new animal drug application or abbreviated new animal drug application. For a drug intended for animal use that is the subject of a conditionally approved application under section 571 of the Federal Food, Drug, and Cosmetic Act, the application number for the conditionally approved new animal drug.

(c) *Veterinary minor species index file number.* For a drug intended for use in animals that is the subject of an Index listing under section 572 of the Federal Food, Drug, and Cosmetic Act, the Minor Species Index File number of the new animal drug on the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species.

(d) *Investigational new animal drug number.* For a drug intended for animal use that is the subject of an investigational new animal drug or generic investigational new animal drug application under part 511 of this chapter, the number of the investigational new animal drug or generic investigational new animal drug file.

§ 1.76 Medical devices.

In addition to the data required to be submitted in § 1.72, an ACE filer must submit the following information at the time of filing entry in ACE for medical devices regulated by the FDA Center for Devices and Radiological Health.

(a) *Registration and listing.* For a medical device, the Registration Number for Foreign Manufacturers, Foreign Exporters, and/or Domestic Manufacturers, and the Device Listing Number, required under section 510 of the Federal Food, Drug, and Cosmetic Act and part 807 of this chapter.

(b) *Investigational devices.* For an investigational medical device that has an investigational device exemption granted under section 520(g) of the Federal Food, Drug, and Cosmetic Act, the Investigational Device Exemption Number. For an investigational medical device being imported or offered for import for use in a nonsignificant risk or exempt study, ''NSR'' to be entered in the Affirmation of Compliance for the ''investigational device exemption'' that identifies the device as being used in a nonsignificant risk or exempt study.

(c) *Premarket number.* For a medical device that has one, the Premarket Number. This is the Premarket Approval Number for those medical devices that have received premarket approval under section 515 of the Federal Food, Drug, and Cosmetic Act; the Product Development Protocol Number for those medical devices for which FDA has declared the product development protocol complete under section 515(f) of the Federal Food, Drug, and Cosmetic Act; the De Novo number for those medical devices granted marketing authorization under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act; the Premarket Notification Number for those medical devices that received premarket clearance under section 510(k) of the Federal Food, Drug, and Cosmetic Act; or the Humanitarian Device Exemption Number for those medical devices for which an exemption has been granted under section 520(m) of the Federal Food, Drug, and Cosmetic Act.

(d) *Component.* If applicable for a medical device, an affirmation identifying that the article being imported or offered for import is a component that requires further processing or inclusion into a finished medical device.

(e) *Lead wire/patient cable.* For electrode lead wires and patient cables intended for use with a medical device, an Affirmation of Compliance with the

applicable performance standard under § 898.12 of this chapter.

(f) *Impact resistant lens.* For impact resistant lenses in eyeglasses and sunglasses, an Affirmation of Compliance with the applicable requirements of § 801.410 of this chapter.

(g) *Convenience kit.* If applicable for a medical device, an Affirmation of Compliance that the article imported or offered for import is a convenience kit or part of a convenience kit.

§ 1.77 Radiation-emitting electronic products.

In addition to the data required to be submitted in § 1.72, an ACE filer must submit all of the declarations required in Form FDA 2877 electronically in ACE at the time of filing entry for products subject to the standards under parts 1020–1050 of this chapter.

§ 1.78 Biological products, HCT/Ps, and related drugs and medical devices.

In addition to the data required to be submitted in § 1.72, an ACE filer must submit the following information at the time of filing entry in ACE for biological products, HCT/Ps, and related drugs and medical devices regulated by the FDA Center for Biologics Evaluation and Research.

(a) *Product name* which identifies the article being imported or offered for import by the name commonly associated with that article including the established name, trade name, brand name, proper name, or product description if the article does not have an established name, trade name, brand name, or proper name.

(b) *HCT/P registration and affirmation.* (1) For an HCT/P regulated solely under section 361 of the Public Health Service Act and the regulations in part 1271 of this chapter that is manufactured by an establishment that is required to be registered under part 1271 of this chapter, the HCT/P Registration Number; and

(2) For an HCT/P regulated solely under section 361 of the Public Health Service Act and the regulations in part 1271 of this chapter, an Affirmation of Compliance with the applicable requirements of part 1271 of this chapter.

(c) *Licensed biological products.* For a biological product that is the subject of an approved biologics license application under section 351 of the Public Health Service Act, the Submission Tracking Number of the biologics license application and/or the Biologics License Number.

(d) *Drug registration.* For a drug intended for human use, the Drug Registration Number if the foreign establishment where the human drug was manufactured, prepared, propagated, compounded, or processed before being imported or offered for import into the United States is required to register the drug under part 207 or part 607 of this chapter as applicable. For the purposes of this section, the Drug Registration Number that must be submitted at the time of entry in ACE is the unique facility identifier of the foreign establishment where the human drug was manufactured, prepared, propagated, compounded, or processed before being imported or offered for import into the United States. The unique facility identifier is the identifier submitted by a registrant in accordance with the system specified under section 510(b) of the Federal Food, Drug, and Cosmetic Act.

(e) *Drug application number.* For a drug intended for human use that is the subject of an approved application under section 505(b) or 505(j) of the Federal Food, Drug, and Cosmetic Act, the number of the new drug application or the abbreviated new drug application.

(f) *Investigational new drug application number.* For a drug intended for human use that is the subject of an investigational new drug application under section 505(i) of the Federal Food, Drug, and Cosmetic Act, the number of the investigational new drug application.

(g) *Medical device registration and listing.* For a medical device subject to the registration and listing procedures contained in part 807 of this chapter, the Registration Number for Foreign Manufacturers, Foreign Exporters, and/or Domestic Manufacturers, and the Device Listing Number, required under section 510 of the Federal Food, Drug, and Cosmetic Act and part 807 of this chapter.

(h) *Investigational devices.* For an investigational medical device that has an investigational device exemption granted under section 520(g) of the Federal Food, Drug, and Cosmetic Act, the Investigational Device Exemption Number. For an investigational medical device being imported or offered for import for use in a nonsignificant risk or exempt study, ''NSR'' to be entered in the Affirmation of Compliance for the ''investigational device exemption'' that identifies the device as being used in a nonsignificant risk or exempt study.

(i) *Medical device premarket number.* For a medical device that has one, the Premarket Number. This is the Premarket Approval Number for those medical devices that have received premarket approval under section 515 of the Federal Food, Drug, and Cosmetic Act; the Product Development Protocol Number for those medical devices for which FDA has declared the product development protocol complete under section 515(f) of the Federal Food, Drug, and Cosmetic Act; the De Novo number for those medical devices granted marketing authorization under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act; the Premarket Notification Number for those medical devices that received premarket clearance under section 510(k) of the Federal Food, Drug, and Cosmetic Act; or the Humanitarian Device Exemption Number for those medical devices for which an exemption has been granted under section 520(m) of the Federal Food, Drug, and Cosmetic Act.

(j) *Medical device component.* If applicable for a medical device, an affirmation identifying that the article being imported or offered for import is a component that requires further processing or inclusion into a finished medical device.

§ 1.79 Tobacco products.

In addition to the data required to be submitted in § 1.72, an ACE filer must submit the following information at the time of filing entry in ACE.

(a) *Brand name* of an article that is a tobacco product that is being imported or offered for import. If the article does not have a specific brand name, the ACE filer must submit a commercial name for the brand name. This data element is not applicable to those products solely intended either for further manufacturing or as investigational tobacco products.

(b) [Reserved]

§ 1.80 Cosmetics.

An ACE filer must submit the data specified in § 1.72 at the time of filing entry in ACE.

§ 1.81 Rejection of entry filing.

FDA may reject an entry filing for failure to provide complete and accurate information that is required pursuant to this subpart.

■ 3. In § 1.83, revise paragraph (a) to read as follows:

§ 1.83 Definitions.

* * * * *

(a) The term *owner* or *consignee* means the person who makes entry under the provisions of section 484 of the Tariff Act of 1930, as amended (19 U.S.C. 1484), namely, the ''importer of record.''

* * * * *

■ 4. Revise § 1.90 to read as follows:

§ 1.90 Notice of sampling.

When a sample of an article offered for import has been requested by the district director, FDA shall provide to the owner or consignee prompt notice of delivery of, or intention to deliver, such sample. Upon receipt of the notice, the owner or consignee shall hold such article and not distribute it until further notice from the district director or U.S. Customs and Border Protection of the results of examination of the sample.

■ 5. In § 1.94, revise the first sentence of paragraphs (a) and (c) to read as follows:

§ 1.94 Hearing on refusal of admission or destruction.

(a) If it appears that the article may be subject to refusal of admission, or that the article is a drug that may be subject to destruction under section 801(a) of the Federal Food, Drug, and Cosmetic Act, the district director shall give the owner or consignee a written or electronic notice to that effect, stating the reasons therefor. * * *

* * * * *

(c) If the article is a drug that may be subject to destruction under section 801(a) of the Federal Food, Drug, and Cosmetic Act, the district director may give the owner or consignee a single written or electronic notice that provides the notice of refusal of admission and the notice of destruction of an article described in paragraph (a) of this section. * * *

PART 1005—IMPORTATION OF ELECTRONIC PRODUCTS

■ 6. The authority citation for part 1005 continues to read as follows:

Authority: 21 U.S.C. 360ii, 360mm.

■ 7. Revise § 1005.2 to read as follows:

§ 1005.2 Definitions.

As used in this part:

The term *owner* or *consignee* means the person who makes entry under the provisions of section 484 of the Tariff Act of 1930, as amended (19 U.S.C. 1484), namely, the ''importer of record.''

PART 1271—HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE–BASED PRODUCTS

■ 8. The authority citation for part 1271 continues to read as follows:

Authority: 42 U.S.C. 216, 243, 263a, 264, 271.

■ 9. In § 1271.420, revise paragraph (a) to read as follows:

§ 1271.420 HCT/Ps offered for import.

(a) Except as provided in paragraphs (c) and (d) of this section, when an HCT/P is offered for import, the importer of record must notify, either before or at the time of importation, the director of the district of the Food and Drug Administration (FDA) having jurisdiction over the port of entry through which the HCT/P is imported or offered for import, or such officer of the district as the director may designate to act in his or her behalf in administering and enforcing this part, and must provide sufficient information, including information submitted in the Automated Commercial Environment (ACE) system or any other electronic data interchange system authorized by the U.S. Customs and Border Protection Agency as required in part 1, subpart D of this chapter, for FDA to make an admissibility decision.

* * * * *

Dated: November 21, 2016.

Leslie Kux,

Associate Commissioner for Policy, Food and Drug Administration.

In concurrence with FDA:

Dated: November 21, 2016.

Timothy E. Skud,

Deputy Assistant Secretary (Tax, Trade, and Tariff Policy), Department of the Treasury.

[FR Doc. 2016–28582 Filed 11–28–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA–2016–N–1896]

New Animal Drugs for Use in Animal Feed; Category Definitions; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of December 1, 2016, for the final rule that appeared in the **Federal Register** of August 24, 2016. The direct final rule amends the animal drug regulations by revising the definitions of the two categories of new animal drugs used in medicated feeds to base category assignment only on approved uses in major animal species. This document confirms the effective date of the direct final rule.

DATES: Effective date of final rule published in the **Federal Register** of August 24, 2016 (81 FR 57796) confirmed: December 1, 2016.

FOR FURTHER INFORMATION CONTACT: David Edwards, Center for Veterinary Medicine (HFV–220), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–6205.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 24, 2016 (81 FR 57796), FDA solicited comments concerning the direct final rule for a 75-day period ending November 7, 2016. FDA stated that the effective date of the direct final rule would be on December 1, 2016, unless any significant adverse comment was submitted to FDA during the comment period. FDA did not receive any significant adverse comments.

Authority: Therefore, under the animal drug provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 354, 360b, 360ccc, 360ccc–1, and 371), and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 558 is amended. Accordingly, the amendments issued thereby are effective.

Dated: November 22, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–28607 Filed 11–28–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–448]

Schedules of Controlled Substances: Temporary Placement of Furanyl Fentanyl Into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final order.

SUMMARY: The Administrator of the Drug Enforcement Administration is issuing this final order to temporarily schedule the synthetic opioid, *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylfuran-2-carboxamide (furanyl fentanyl), and its isomers, esters, ethers, salts and salts of isomers, esters and ethers, into schedule I pursuant to the temporary scheduling provisions of the Controlled Substances Act. This action is based on a finding by the Administrator that the placement of furanyl fentanyl into schedule I of the Controlled Substances Act is necessary to avoid an imminent hazard to the public safety. As a result of this order, the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances will be imposed