

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 1005, and 1271

[Docket No. FDA-2016-N-1487]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is proposing 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, foster U.S. economic security through lawful international trade and policy, and to replace the Automated Commercial System (ACS). FDA is a Partner Government Agency (PGA) in the initiative to establish ITDS, the “single window” for the submission of import and export data to the United States Government. The proposed rule would also update certain sections of FDA regulations related to imports. This rule, as proposed, does not affect the ability of filers to continue to submit their import entries and entry summaries by paper for FDA-regulated products that are being imported or offered for import. Once finalized, this action 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: Submit either electronic or written comments on the proposed rule by August 30, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions.”)

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2016-N-1487 for “Submission of FDA Import Data into the Automated Commercial Environment.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including

the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, 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.

Submit comments on information collection issues under the Paperwork Reduction Act of 1995 to the Office of Management and Budget (OMB) in the following ways:

- Fax to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or email to oir_submission@omb.eop.gov. All comments should be identified with the title, “Submission of FDA Import Data into the Automated Commercial Environment.”

FOR FURTHER INFORMATION CONTACT: 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: Jonnalynn Capezzuto, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., Rm. 14526, Silver Spring, MD 20993-0002, Jonnalynn.Capezzuto@fda.hhs.gov.

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I. Executive Summary

A. Purpose of the Proposed Rule

The proposed rule would require that certain data elements material to our admissibility determination on FDA-regulated products being imported or offered for import, be submitted in ACE or any other CBP-authorized EDI system, at the time of entry. This action, once finalized, 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.

FDA also proposes to make technical revisions to certain sections of FDA

regulations to make updates and provide clarifications.

B. Summary of the Major Provisions of the Proposed Rule

This proposed rule would add Subpart D to Part 1 of 21 CFR Chapter I 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).

The proposed rule would also make technical revisions to certain sections of 21 CFR Chapter I to update them. We propose to revise 21 CFR 1.83 and 21 CFR 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 propose to revise 21 CFR 1.90 to allow FDA to provide notice of sampling directly to an owner or consignee. Additionally, we propose to revise 21 CFR 1.94 to clarify that written notice can be provided electronically by FDA to owners or consignees of FDA actions to detain, refuse, and/or subject certain products to administrative destruction. Under § 1.94, owners or consignees will 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 are also proposing to amend 21 CFR 1271.420 to make clear that, unless otherwise exempt, importers of record of human cells, tissues and cellular and tissue-based products (HCT/Ps) that are regulated solely under section 361 of the Public Health Service Act (42 U.S.C. 264) and 21 CFR part 1271 would be required to submit the applicable data elements included in the proposed rule in ACE.

C. Legal Authority

The legal authority for the proposed 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 Public Health Service Act (PHS Act) (42 U.S.C. 262, 264, and 271, respectively).

D. Costs and Benefits

The Agency has determined that this proposed rule may be a significant regulatory action as defined by Executive Order 12866. Although at this time we cannot fully quantify the benefits of this proposed rule, adopting the proposed rule is expected to provide a positive net benefit (estimated benefits minus estimated costs) to society.

II. Table of Abbreviations/Commonly Used Acronyms 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.
Agency	U.S. Food and Drug Administration.
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.
ITDS	International Trade Data System.
OASIS	FDA 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

The number of FDA-regulated products imported into the United States has grown steadily, from

approximately 6 million import lines in 2002 to over 35 million import lines in 2015. In 2014, FDA-regulated products imported or offered for import were

manufactured in more than 322,500 foreign facilities and arrived in the United States from more than 100 countries. This increase in the

importation of FDA-regulated products has posed challenges to FDA including enforcement of sections 536 and 801 of the FD&C Act and sections 351, 361, and 368 of the PHS Act.

Section 484 of the Tariff Act of 1930 as amended (19 U.S.C. 1484) established the requirement for importers of record to make entry for merchandise imported into the customs territory of the United States. When goods are imported into the United States they must be *entered* at one of the CBP ports. The term *entry* refers to the information or documentation that an importer of record must file with CBP. An *import line* is each portion of an import entry that is listed as a separate item on an entry document.

An importer of record is the owner or purchaser of the article being 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 one importer of record per entry. Approximately 98 percent of all entries containing FDA-regulated products subject to the proposed rule are filed by customs brokers.

In December 1993, the Customs Modernization Act (Title VI of the North American Free Trade Agreement Implementation Act (Pub. L. 103–182)) was enacted. A prominent feature of the Customs Modernization Act is the legal requirement that importers of record exercise *reasonable care* when filing entries (19 U.S.C. 1484). Reasonable care requires that CBP be provided with the accurate and complete information or documentation deemed necessary by CBP to determine whether all legal requirements for admissibility of that article have been met.

The Customs Modernization Act also included the development of ACE, the planned successor to ACS which has been the electronic system used by CBP to track, control, and process all commercial goods imported into the United States for decades. ACE is intended to streamline business processes, facilitate growth in trade, ensure cargo security, and foster participation in global commerce while ensuring compliance with U.S. laws and regulations.

The ITDS, as described in section 405 of the Security and Accountability for Every Port Act of 2006 (SAFE Port Act) (Pub. L. 109–347), was established to modernize and simplify the way in which PGAs, including FDA, interact with importers by creating a “single window” through which industry will transmit the data elements required for importation or exportation of cargo. The purpose of ITDS is to eliminate

redundant filing requirements, to efficiently regulate the flow of commerce, and to effectively enforce laws and regulations relating to international trade, by establishing a single portal system, operated by CBP, for the collection and distribution of standard electronic import and export data required by all PGAs (19 U.S.C. 1411(d)(1)(B)). CBP has designed ACE to provide that “single window” for the filing of entries. Over the last several years, CBP has tested ACE and provided significant public outreach to ensure that the trade community is fully aware of the transition from ACS to ACE (81 FR 10264, February 29, 2016). FDA has actively participated as a PGA in the development of ITDS and ACE.

On February 19, 2014, President Obama issued an Executive Order, *Streamlining the Export/Import Process for America's Businesses* (Executive Order 13659), requiring that, by December 31, 2016, PGAs have the capabilities, agreements, and other requirements in place to utilize the ITDS and supporting systems, such as ACE as the primary means of receipt of the data and other relevant information necessary for the release and clearance of imported goods. Executive Order 13659 envisions a simpler, more efficient automated system for trade use for the benefit of both the trade industry and PGAs. ACE is expected to become the sole EDI system authorized by CBP for processing electronic entry and entry summary filings; ACS incrementally is being decommissioned by CBP for those functions.

While primary responsibility for administering U.S. laws relating to imports is exercised by CBP, FDA is responsible for determining whether or not an FDA-regulated article being imported or offered for import is in compliance with the laws enforced by FDA. The discharge of this joint responsibility has involved close coordination and cooperation between FDA and CBP for such imports.

FDA receives notice from CBP of the arrival at each U.S. port of entry (sea, land, rail, and air) where FDA-regulated products are imported, of each shipment containing an FDA-regulated product. The PGA Message Set in ACE for FDA-regulated products contains the data that assists FDA in determining the admissibility of those products under FDA authorities. This data is transmitted to CBP by an ACE filer through the Automated Broker Interface (ABI), which permits a participant to file import data electronically in ACE. ABI is the primary mechanism for data submission in ACS, and will continue to be used in ACE. After the data is

submitted through ABI in ACE, it is validated by CBP and made available to FDA. Transmission of data via ABI enables more effective enforcement and faster release decisions, as well as more certainty for the importer in determining logistics of cargo delivery (81 FR 10264). ABI is available to brokers, importers, and independent service bureaus, and currently over 96 percent of all entries filed with CBP in ACS are filed through ABI (Ref. 1).

If a required data element is not submitted in ACE, CBP cannot process the entry. The ACE filer will then receive an electronic message indicating that a particular data element was missing and that the entry will not be processed without submission of that data element. The ACE filer may refile the entry and it will be processed by CBP if all of the required elements are submitted.

Because, under ACE, CBP will relay the data in the PGA Message Set to FDA using an electronic interface with OASIS, the ACE filer will only need to submit this entry information once provided that the information submitted in ACE is accurate. ACE entries will be electronically screened in OASIS against criteria developed by FDA, as they were in ACS. FDA's Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) is a risk-based electronic screening tool for OASIS that performs this initial electronic screening to assist FDA entry reviewers by evaluating the potential risks associated with each article, and identifying those articles that may present a higher public health risk for further examination by FDA.

OASIS expedites the clearance of FDA-regulated products that present a low public health risk but only if the importer of record provides accurate and complete import information. If the FDA electronic screening evaluation of the potential public health risk is determined to be low, OASIS will transmit a message back through the FDA/CBP interface that indicates an article being imported or offered for import “May Proceed” into U.S. commerce, barring any alternate determination by CBP. A “May Proceed” message does not constitute a determination by FDA about the article's compliance status, and it does not preclude FDA action at a later time. If the FDA electronic review determines that further evaluation by FDA is necessary, FDA personnel will manually review the entry information submitted by the ACE filer and may request additional information to make an admissibility determination and/or may

examine or sample the FDA-regulated article.

CBP collects in ACS four data elements to assist FDA in making admissibility decisions for FDA-regulated products: (1) The complete FDA Product Code; (2) FDA country of production; (3) FDA manufacturer and shipper; and (4) the ultimate consignee. Under the proposed rule, two of these data elements would be mandatory submissions at the time of entry in ACE or any other CBP-authorized EDI system: The complete FDA product code and FDA Country of Production.

In ACS, filers are also able to make optional submissions of certain information such as Affirmations of Compliance regarding requirements related to the FDA-regulated product. By submitting data using an Affirmation of Compliance Code, the filer affirms that the firm or FDA-regulated article identified in an entry line meets the requirements specific to each Affirmation of Compliance Code. FDA publishes a list of current Affirmation of Compliance Codes on the FDA Web site at <http://www.fda.gov/forindustry/importprogram/entryprocess/entrysubmissionprocess/ucm461234.htm>.

Submissions of Affirmations of Compliance 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." The number of Affirmation of Compliance submissions in ACS has varied depending on the commodity. For example, in 2015 approximately 98 percent of entry lines that are or include a medical device have at least one Affirmation of Compliance Code submitted in ACS, but only 24 percent of entry lines that are or include an animal drug have at least one of the Affirmations of Compliance Codes.

We propose to make mandatory, at the time of entry in ACE, submission of certain data elements (that have been submitted in ACS) in order to more effectively and efficiently screen for those FDA-regulated products which are likely to pose a low public health risk. 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 FDA reviewers either search for that information in our data systems or request 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 FDA and the

importer than a manual review. For example, the average time for the OASIS system to process an import entry submitted in ACS in 2015 and issue an automated "May Proceed" determination was approximately 24 minutes whereas the average time for an FDA-reviewer to manually review and issue a "May Proceed" determination was about 28 hours. FDA expects that mandatory submission of these data elements will increase the number of import entries of FDA-regulated products that receive an automated "May Proceed" determination. The average time for FDA to issue an automated "May Proceed" determination is expected to be faster for entries to be submitted in ACE than it was for entries submitted in ACS. As a result of a more streamlined import process, the proposed rule is expected to lead to a more effective use of FDA and importer resources, and more efficient enforcement of section 801(a) of the FD&C Act.

The PGA Message Set in ACE also includes optional submission of information relevant to FDA's admissibility determination on FDA-regulated products. We strongly encourage ACE filers to submit the optional data elements in the PGA Message Set at the time of entry if the importer of an FDA-regulated product is interested in an expedited admissibility review on its products by the Agency (see the FDA Supplemental Guidance which includes the optional data elements published at: <http://www.fda.gov/downloads/ForIndustry/ImportProgram/UCM459926.pdf>). Accurate and complete information submitted by an ACE filer increases the likelihood that an entry line will receive an automated "May Proceed" determination from FDA.

For example, the PGA Message Set in ACE contains optional active pharmaceutical ingredient (API) data elements for finished human and animal drugs. The API data elements include the name of the API, the amount and unit of measure of the API in the finished drug, and the name of the manufacturer of the API in the finished drug. FDA believes that submission of this additional information may expedite import entry review by facilitating electronic "May Proceed" determinations for low risk drugs. FDA invites comments on the advantages, disadvantages, and feasibility of providing these API data elements for human and animal drugs, if they were to become mandatory data elements for entry filing in ACE.

FDA also invites 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 propose 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 invite comment on whether the submission of these data elements will 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.

Additionally, FDA invites 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 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. Submission of intended use codes assists us in differentiating between products in the same product category which may have the same product code. For example, an ACE filer would submit in ACE at the time of entry an intended use code "For Human Medical Use as a Medical Device" as the intended use for a medical device, accessory, or component that is regulated as a finished medical device for use in humans. Use of another intended use code would inform the Agency that the finished medical device for use in humans is only to be used for research and development as a medical device, for bench testing or nonclinical research use or as a device sample for customer evaluation.

By submitting a disclaimer in ACE at the time of entry, the 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.

In particular, we invite 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, if they were to become mandatory FDA data elements for entry filing in ACE.

FDA announced its participation in the National Customs Automation Program (NCAP) test in the **Federal Register** in August 27, 2015 (80 FR 52051). An increasing number of filers

are currently filing entries of FDA-regulated products in ACE. Although our NCAP test ended May 2, 2016, CBP is allowing the filing of entries for FDA-regulated products in ACS to continue in order to provide more time for the trade community to transition to ACE (81 FR 18634, March 31, 2016). In the **Federal Register** on May 16, 2016 (81 FR 30320), and May 23, 2016 (81 FR 32339), CBP announced that effective June 15, 2016, and July 23, 2016, respectively, ACE will be the sole EDI system for electronic entry and entry summary filings for merchandise specified in the notices and subject to the import requirements of FDA, and ACS will no longer be a CBP-authorized EDI system for purposes of processing such filings. CBP will continue to monitor FDA filing rates in ACE and should there be a need to avoid a substantial adverse impact on trade, CBP will reassess the transition completion date for FDA filings (81 FR 30320 at 30321).

IV. Legal Authority

FDA has 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 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 proposed 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 proposed rule under authority granted to FDA by section 801(r) of the FD&C Act (21 U.S.C. 381(r)), 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) 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. These regulations would be jointly prescribed by FDA and the Department of the Treasury, with the exception of the provisions of the proposed 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. Description of the Proposed Rule

We propose to add subpart D to part 1 of 21 CFR Chapter I to require certain data elements for FDA-regulated products to be submitted in ACE or any other CBP-authorized EDI system, at the time the electronic entry is filed. If an ACE filer fails to submit any of the data elements specified in proposed subpart D applicable to the entry, the entry will be rejected. All but four of the data elements specified in proposed subpart D are currently collected in ACS. The

two new required submissions in proposed § 1.72 which apply to food contact substances, drugs, biological products, HCT/Ps, medical devices, radiation-emitting electronic products, cosmetics, and tobacco products, are a name, telephone number, and email address for one of the persons related to the importation of the product, which may include the manufacturer, shipper, importer of record, or Deliver to Party, and a telephone number and email address for the importer of record which we need to facilitate electronic notice under § 1.94 for certain FDA actions. The two other new required data elements, in proposed 21 CFR 1.79, are name and address of the ACE filer and brand name for tobacco products.

FDA is also proposing to make technical and clarifying amendments to parts 1 and 1005 to update certain sections of those regulations. The updates include striking references to statutes or procedures no longer in effect and clarifying that electronic notice can be given of FDA actions related to a product that is being imported or offered for import. The proposed technical amendments to part 1 consist of amendments to §§ 1.83, 1.90, and 1.94. The proposed technical amendment to part 1005 consists of an amendment to § 1005.2.

We are also proposing to revise § 1271.420 to make clear that the applicable requirements of the proposed rule would apply to HCT/Ps that are regulated solely under section 361 of the PHS Act and part 1271, except those HCT/Ps that would otherwise be exempt from these requirements.

A. Scope/Applicability

The proposed rule would apply to the submission of import entries in ACE or any other CBP-authorized EDI system for certain foods, drugs, medical devices, radiation-emitting electronic products, biological products, HCT/Ps, cosmetics, and tobacco products regulated by FDA.

B. Definitions

The proposed rule contains a number of definitions for terms used in the rule. These definitions are based on existing definitions in statutes or other FDA regulations, or are definitions commonly used by industry.

C. Data Elements that Must Be Submitted in ACE for FDA-Regulated Products

1. General Data Elements for FDA-Regulated Commodities

The proposed rule would require that the following data elements be

submitted at the time of entry in ACE or any other CBP-authorized EDI system, for food as applicable, drugs, biological products, HCT/PS, medical devices, radiation-emitting electronic products, cosmetics, and tobacco products. The specific information to be submitted may vary depending on the article being imported or offered for import.

The required FDA data elements in the proposed rule are in addition to the data elements CBP requires for submission in ACE. The FDA required data elements specified in proposed § 1.72 generally fall into two categories: Those data elements that identify the article being imported or offered for import and those data elements that identify the person(s) who are seeking to import the article into the United States. This additional information will assist us in our efforts to more effectively and efficiently determine the admissibility of the article being imported or offered for import. All but two of the general data elements in proposed § 1.72—name, telephone number, and email address for one of the persons related to the importation of the product which may include the manufacturer, shipper, importer of record, or Deliver to Party, and telephone number and email address of the importer of record—are currently collected in ACS.

a. *Product identification information.* By more precisely identifying the article being imported or offered for import, FDA can determine what statutory and regulatory requirements apply to that article. The product identification information that FDA proposes to be required in submissions at the time of entry in ACE includes:

i. *FDA country of production.* The FDA Country of Production identifies the country where an FDA-regulated article was last manufactured, processed or grown (including harvested or collected and readied for shipment to the United States).

The FDA Country of Production may be different than the Country of Origin required by CBP for an article that is being imported or offered for import. The country of origin as defined by CBP is the country of manufacture, production or growth of the article. There is only one country of origin for each article. 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. The substantial

transformation test is applied by the importer of record to the facts and circumstances of each case. The FDA Country of Production, however, is the country where the article last underwent any manufacturing or processing but only if such manufacturing or processing was of more than a minor, negligible or insignificant nature.

ii. *The complete FDA Product Code.* The FDA Product Code is an alphanumeric code that is used by us for classification and analysis of regulated products. The FDA Product Code builder application is currently available on FDA’s Web site at <http://www.accessdata.fda.gov/SCRIPTS/ORA/PCB/PCB.HTM>. The Product Code builder application allows ACE filers to locate or build the appropriate FDA Product Code. The FDA Product Code is based on the following five components.

- Industry designates the broadest area into which a product falls;
- class is directly related to an industry and designates the food group, source, product, use, pharmacological action, category, or animal species of the product;
- subclass designates the container type, method of application, use, market class, or type of product and relates directly to a particular Industry grouping by utilizing a unique set of definitions specific to those products;
- Process indicator code specifies the process, storage or dosage form depending on the type of product; and
- product relates to a particular industry/class combination.

The complete FDA Product Code is a critical data element for our admissibility review because it clearly identifies the type of article that is being entered in ACE, which allows FDA to determine which statutory and/or regulatory requirements apply to that article. Under the proposed rule, the complete FDA Product Code entered in ACE would be required to agree with the invoice description of the article.

iii. *FDA Value.* FDA is proposing 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. CBP requires that the value of an entry based on the invoice value of the shipment in U.S. dollars (rounded off to the nearest whole dollar) be submitted in ACE at the time of entry. Submission by an ACE filer of the value of an entry is necessary because all goods imported into the United States are subject to the provisions of the Harmonized Tariff Schedule of the United States, Annotated for Statistical Reporting Purposes (HTS), that is published by the

U.S. International Trade Commission as directed by Congress in section 1207 of the Omnibus Trade and Competitiveness Act of 1988 (Pub. L. 100–418; 19 U.S.C. 3007) regarding any duties to be paid for importation of the article(s) contained in that entry. For FDA-regulated products, we propose to allow the ACE filer to choose whether to submit the total value of the entry as reported to CBP or to apportion the value of the entry to the total value of the article(s) in each import line at the time of entry in ACE. If an ACE filer chooses to submit the total value for the article(s) in each import line, that value must match the total invoice value of the article(s) in that import line.

We invite 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 invite 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 will 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.

iv. *FDA Quantity.* FDA is proposing to require submission of the quantity of the FDA-regulated article(s) in each import line at the time of entry in ACE. 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). An example of a quantity description that would be submitted in ACE at the time of entry includes these layer/levels of packaging: 200 cases of surgical gauze, 100 rolls per case and 75 square yards of surgical gauze per roll.

Quantity and packaging help us identify the article as a specific FDA-regulated product. Although CBP and FDA utilize the HTS codes to generally identify which imports are subject to an FDA admissibility review, these codes are often not sufficient to specifically identify a product for FDA decisionmaking. There are several products that FDA considers to be different from each other because of how the product is packaged. Packaging can also affect the potential safety of an FDA-regulated product particularly where an article is represented at time of entry as “sterile.” In addition, FDA

submission of the quantity in ACE at the time of entry would assist the Agency in performing any needed followup action on an entry line such as field examinations, label examinations, sample collections, detentions, and refusals. Thus, the initial availability of quantity per import line would increase efficiency and expedite FDA activities throughout the admissibility process.

We invite 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 invite comment on whether the submission by an ACE filer of the FDA quantity of the article(s) in an import line will 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.

b. Entity identification information.

i. Entity contact information. The proposed rule would 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. This information would facilitate FDA's decisionmaking on admissibility of an entry because FDA would have the information to quickly and easily contact a person with knowledge of the entry regarding questions about the entry and/or a particular import line in the entry.

We invite 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 invite comment on whether the submission by an ACE filer of this information will 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.

ii. Importer of record contact information. We are proposing to require that the email and phone number of the importer of record be submitted in ACE at the time of entry. This information will provide us with the contact information for the importer of record to enable us to contact that person with any questions about the import entry as well as send notices of FDA Actions such as detention, refusal, and/or administrative destruction electronically to that person.

We are proposing to revise § 1.94 to clarify that electronic notice may be sent by the Agency to the owner or consignee, which will be defined in § 1.83 as the importer of record, for detention, refusal, and/or administrative destruction of an FDA-regulated article being imported or offered for import into the United States. A refused drug valued at \$2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) is subject to administrative destruction (section 801(a) of the FD&C Act). Obtaining a current email address for the importer of record is critical to FDA's ability to provide such electronic notice. We are also requiring a telephone number to contact the importer of record in the event that the email address submitted in ACE is incorrect or out of date.

2. Food

For purposes of this rule, food means foods as defined in section 201(f) of the FD&C Act (21 U.S.C. 321(f)) (see proposed § 1.71(i)). Examples of food covered by this rule include fruits, vegetables, fish, including seafood, dairy products, eggs, raw agricultural commodities for use as food or as components of food, animal feed (including pet food), food and feed ingredients, food and feed additives, dietary supplements and dietary ingredients, infant formula, beverages (including alcoholic beverages and bottled water), live food animals, bakery goods, snack foods, candy, and canned foods.

One aspect of importation of food via ACS and ACE is regulated under the Prior Notice of Imported Food regulation, part 1, subpart I. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107-188) (the BT Act) amended the FD&C Act by adding section 801(m) requiring prior notification of imported food. In accordance with section 801(m)(1) of the FD&C Act, we published a final rule in the **Federal Register** on November 7, 2008 (73 FR 66294).

For every article of food imported or offered for import into the United States, except those articles identified in §§ 1.276(b)(5)(i) and 1.277(b), the information required under § 1.281 must be submitted in ACS or the FDA Prior Notice System Interface (PNSI) before the arrival of that food article in the United States. Food articles imported or offered for import without adequate prior notice are subject to refusal under section 801(m) of the FD&C Act. The prior notice regulation under § 1.280 requires that prior notice information be submitted via ACS or via PNSI. We

issue a Prior Notice Confirmation Number (PN Confirmation Number) when prior notice has been submitted and confirmed for review (§ 1.279(d)). We use prior notice information to make decisions, based on public health risk, about which food to inspect at the port of arrival.

If the prior notice information required under § 1.281 for a food article is submitted via ACS simultaneously with the required entry information, no additional transmission of information for the admissibility determination on that food article under section 801(a) of the FD&C Act is necessary. If prior notice is submitted via PNSI, additional transmission via ACS for the import entry may be necessary for CBP purposes and FDA's admissibility determination under section 801(a) of the FD&C Act (see 68 FR 58976, October 10, 2003). The PN Confirmation Number must be submitted into ACS at the time of the food's arrival into the United States under § 1.279(g).

This proposed rule does not address or impact the current import entry review process for food articles requiring prior notice; this process will be operationally transitioned from ACS to ACE.

a. FDA Value. We are proposing to require the submission in ACE at the time of entry of the FDA Value described in § 1.72(a)(3) of the proposed rule, for all food being imported or offered for import into the United States. FDA Value is explained earlier in the General Data Elements for FDA-Regulated Commodities section. As noted in that section, we are inviting comments on the advantages, disadvantages, and feasibility of requiring an ACE filer to submit this information in ACE at the time of entry.

b. Food contact substances. For the purposes of prior notice, food contact substances are exempted from the definition of food under § 1.276(b)(5)(i)(A) and are, therefore, not subject to the requirements under the prior notice regulation. We are proposing to require the submission in ACE at the time of entry of the general data elements described in § 1.72 of the proposed rule, for food contact substances being imported or offered for import into the United States. This additional information will assist us in our efforts to more effectively and efficiently determine admissibility of the food contact substance being imported or offered for import.

c. Acidified and low-acid canned food data. If the article of food being imported or offered for import is an acidified food (AF) or a thermally processed low-acid canned food

packaged in a hermetically sealed container (LACF), we propose 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.

Although some hermetically sealed containers (e.g., pouches and glass bottles) used to package thermally processed low-acid food would not be viewed as “cans”, the term “low-acid canned food” has been used for decades as a shorthand description for “thermally processed low-acid foods packaged in hermetically sealed containers”. We continue to use that term (and its abbreviation, LACF) for the purposes of this document.

Botulism, a rare but serious paralytic illness that can be fatal, is one of the serious public health risks associated with inadequate or improper manufacture, processing or packaging of AF and LACF. Every commercial processor, when engaging in the manufacture, processing, or packing of an AF or LACF, is required to register and file with FDA information including the name of the establishment, principal place of business, the location of each establishment in which the processing of acidified foods or low-acid canned foods is carried on, the processing method, and a list of foods so processed in each establishment. (21 CFR 108.25(c)(1) and (j); 21 CFR 108.35(c)(1) and (k)). After an establishment is registered, FDA assigns a unique FCE number identifying the physical processing plant located at the address on the registration form (currently Form FDA 2541). The FCE registration requirement in 21 CFR part 108 for LACF and AF commercial processors is different from the Food Facility Registration (FFR) that is required under section 415 of the FD&C Act (21 U.S.C. 350d) for domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States. The registration requirement in section 415 of the FD&C Act was created by the BT Act and amended by the FDA Food Safety Modernization Act (Pub. L. 111–353). AF and LACF commercial processors must register with FDA as required in part 108 using Form FDA 2541, and must also register with FDA under the FFR system using Form FDA 3537 as required by section 415 of the FD&C Act. We use the term “FFR” interchangeably with the term “BT Act registration.”

After registering, the commercial processor must also, no later than 60

days after registering with FDA and before packing a new product, provide FDA with information on the scheduled processes for each AF and LACF in each container size (§ 108.25(c)(2) and (j); § 108.35(c)(2) and (k)). When processors submit a process filing form, they include the FCE number for the location of the processing plant where the product will be manufactured, processed, or packed. The FCE number on the process filing form links the process filing to the establishment (Ref. 2).

The filed scheduled process is required to provide certain information relevant to the processing of each AF and LACF, including information related to heat during processing, among other requirements (§§ 108.25(c)(2) and 108.35(c)(2)). A manufacturer of an AF and LACF product, such as canned corn in brine, is required to file separate scheduled processes for each type and sized container.

When processors use the electronic AF/LACF system to create a process filing, the system automatically generates a SID. When the processor creates a process filing using a paper form, the processor generates the SID and includes it on the paper form. A SID identifies each process filing, and consists of the year, month, and day of the month that a process filing form is created, and a unique sequence number to identify each form when multiple forms are created on the same day. An FCE can have multiple SIDs. The SID enables both the commercial processor and FDA to quickly and accurately identify a specific process filing.

To effectively identify an AF or LACF article that is being imported or offered for import, we need information regarding that product’s FCE, SID, and can dimensions or volume. This information allows us to match the specific AF or LACF article being imported or offered for import to the applicable scheduled process and processing facility. We may use this information to verify that the scheduled processes filed for each LACF or AF corresponds to the FCE and SID submitted at the time of entry. Such identifying information assists FDA in efficiently enforcing section 801 of the FD&C Act in that it assists FDA in determining the admissibility of a given article.

3. Human Drugs

Globalization of the pharmaceutical market in the United States has resulted in dramatic increases in drug imports, complex and fragmented global supply chains, and increasing threats from counterfeit and substandard drugs.

This rule proposes to make certain information pertaining to imports of drugs regulated by FDA’s CDER that importers can submit in ACS, required submissions in ACE or any other CBP-authorized EDI system.

a. *Registration and Listing.* All persons who own or operate domestic establishments that engage in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs must annually register with FDA, with limited exceptions (section 510(b) of the FD&C Act (21 U.S.C. 360(b)); 21 CFR part 207). Every person who owns or operates any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug that is being imported or offered for import into the United States, is required to annually register with FDA (section 510(i) of the FD&C Act). Each annual establishment registration must include a unique facility identifier (UFI) for each establishment under section 510(b) and (i) of the FD&C Act. Every person who registers must, at the time of registration, also file with FDA a list of all drugs they manufacture, prepare, propagate, compound, or process for commercial distribution in the United States (section 510(j) of the FD&C Act). Registration of foreign establishments must include the name of each importer of the firm’s drugs that is known to the establishment and the name of each person who imports or offers for import such drugs to the United States for purposes of importation (section 510(j) of the FD&C Act).

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

Currently the Affirmation of Compliance Code for submission of the Drug Registration Number is “REG”.

The rule would also require the submission of the Drug Listing Number in ACE. Each listed drug associated with a registration must include a unique identifier. Currently we use the “National Drug Code” (NDC) numbering system as that unique identifier. An NDC is a unique three-segment identifier that identifies the labeler, product (including, for example, specific strength and dosage form), and trade package. For purposes of this proposed rule, the Drug Listing Number is the NDC of the drug being imported

or offered for import. The current Affirmation of Compliance Code for submission of the drug listing number is “DLS”.

Failure to register or list in accordance with section 510 of the FD&C Act causes a drug to be misbranded under section 502(o) of the FD&C Act (21 U.S.C. 352(o)). Drugs that appear to be misbranded are subject to detention and refusal under section 801(a) of the FD&C Act.

b. *Drug application number.* A new drug must be approved by FDA before it can be marketed in the United States (section 505(a) of the FD&C Act (21 U.S.C. 355(a))). A new drug application (NDA) must be submitted to the Agency for the sale or marketing of a new drug (section 505(b) of the FD&C Act). An abbreviated new drug application (ANDA) must be submitted to the Agency for the sale or marketing of a generic drug (section 505(j) of the FD&C Act). FDA issues a unique number for each NDA or ANDA, and that number would be required to be submitted in ACE at the time of entry for each drug that is subject to an approved NDA or ANDA, under the proposed rule.

CDER also regulates certain biological products. Although the majority of therapeutic biological products are licensed under section 351 of the PHS Act, some protein products historically have been approved under section 505 of the FD&C Act. The Biologics Price Competition and Innovation Act of 2009 (BPCI Act) changed the statutory authority under which certain protein products will be regulated by amending the definition of a “biological product” in section 351(i) of the PHS Act to include a “protein (except any chemically synthesized polypeptide).” Section 7002(e) of the BPCI Act requires that a marketing application for a biological product must be submitted under section 351 of the PHS Act, subject to certain exceptions during a 10-year transition period ending on March 23, 2020. On March 23, 2020, an approved application for a biological product under section 505 of the FD&C Act will be deemed to be a license for the biological product under section 351 of the PHS Act (section 7002(e)(4) of the BPCI Act) (Ref. 3). The number of the biologics license application (BLA) or the NDA is required to be submitted at the time of entry in ACE.

Currently the Affirmation of Compliance Code for submission of the NDA, ANDA, or BLA number in ACE is “DA”.

c. *Investigational new drug application number.* The proposed rule mandates that the number of the investigational new drug application

(IND) be submitted in ACE at the time of entry for a drug that is subject to an IND and is being imported or offered for import into the United States. An investigational new drug is a new drug that is used in a clinical investigation (section 505(i) of the FD&C Act and 21 CFR 312.3(b)). An investigational new drug for which an IND is in effect is exempt from the premarket approval requirements that are otherwise applicable and may be shipped lawfully for the purpose of conducting clinical investigations of that drug (part 312). Additionally, an investigational new drug for which an IND is not yet in effect may be shipped lawfully to an investigator named in the IND if the sponsor has received earlier FDA authorization to ship the drug (§ 312.40(c)(2)).

Currently the Affirmation of Compliance Code for submission of the investigational new drug application number is “IND”.

4. Animal Drugs

In broad outline, the data elements required to be submitted in ACE or any other CBP-authorized EDI system, for importation of animal drugs under the proposed rule tracks those required for human drugs. The proposed rule makes certain information, pertaining to animal drug imports that importers can optionally submit in ACS, required submissions in ACE at the time of entry. As in the case of human drugs, a more streamlined import process could lead to a more effective use of FDA and importer resources, and more efficient enforcement of section 801(a) of the FD&C Act for animal drugs.

a. *Registration and listing.* All persons who own or operate domestic establishments that engage in the manufacture, preparation, propagation, compounding, or processing of an animal drug or drugs, must annually register with FDA, with limited exceptions (section 510(b) of the FD&C Act; part 207). Every person who owns or operates any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of an animal drug that is imported or offered for import into the United States is required to annually register with the FDA (section 510(i) of the FD&C Act). Each annual establishment registration must include a UFI for each establishment under section 510(b) and (i) of the FD&C Act). Every person who registers must, at the time of registration, also file with FDA a list of all drugs they manufacture, prepare, propagate, compound, or process for commercial distribution in the United

States (section 510(j) of the FD&C Act). Registration of foreign establishments must include the names of each importer of the firm’s drugs that is known to the establishment and the name of each person who imports or offers for import such drugs to the United States for purposes of importation (section 510(i) of the FD&C Act).

This rule would require the submission in ACE of the Animal Drug Registration Number at the time of entry. For purposes of this proposed rule, the Animal Drug Registration Number that would be submitted in ACE is the UFI 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.

Currently the Affirmation of Compliance Code for submission of the Animal Drug Registration Number is “REG”.

The rule would also require the submission of the Animal Drug Listing Number at the time of entry in ACE. Each listed animal drug associated with a registration must include a unique identifier. Currently we use the NDC numbering system as that unique identifier. An NDC is a unique three-segment identifier that identifies the labeler, product (drug formulation), and trade package. For purposes of this proposed rule, the Drug Listing Number is the NDC of the animal drug being imported or offered for import. The current Affirmation of Compliance Code for submission of the Animal Drug Listing Number is “NDC”.

Failure to register and list in accordance with section 510 of the FD&C Act causes an animal drug to be misbranded under section 502(o) of the FD&C Act. Animal drugs that appear to be misbranded are subject to detention and refusal under section 801(a) of the FD&C Act.

b. *New animal drug application and the minor species index file.* A new animal drug must be approved, conditionally approved, or index listed by FDA before it can be legally marketed in the United States (sections 512(a)(1)(A), 571, and 572 of the FD&C Act (21 U.S.C. 360b(a)(1)(A), 360ccc, and 360ccc-1)). A new animal drug is defined, in part, as a drug intended for use in animals other than man, including any drug intended for use in animal feed, which is not generally recognized by experts as safe and effective for use under the conditions prescribed, recommended, or suggested in its labeling (section 201(v) of the

FD&C Act). Animal feed is defined in section 201(w) of the FD&C Act.

FDA issues a unique number for each new animal drug application (NADA), abbreviated new animal drug application (ANADA), and conditionally approved new animal drug application (CNADA) submitted to the Agency for approval to market a new animal drug. For a new animal drug that is subject to an approved application under section 512(b)(1) or (2) of the FD&C Act, the number corresponding to the NADA or ANADA, respectively, is required to be submitted in ACE at the time of entry under the proposed rule. Under the proposed rule, for new animal drugs that are subject to a conditionally approved application an ACE filer would be required to submit in ACE at the time of entry the number corresponding to the conditionally approved application (section 571 of the FD&C Act).

Under the proposed rule, the Minor Species Index File number (MIF) of the new animal drug on the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species (Index) would be required to be submitted in ACE at the time of entry for articles that are being imported or offered for import that are legally marketed as unapproved new animal drugs for minor species (section 572 of the FD&C Act).

The Minor Use and Minor Species Animal Health Act of 2004 (Pub. L. 108–282) (MUMS Act) signed into law on August 2, 2004, amended the FD&C Act to provide animal drug companies with incentives to develop new animal drugs for minor species and minor uses in major species, while still ensuring appropriate safeguards for animal and human health. The index is limited to minor species for which there is reasonable certainty the animal or edible products from the animal will not be consumed by humans or food-producing animals. Minor species are those animals, other than humans, that are not one of the major species (horses, dogs, cats, cattle, pigs, turkeys, and chickens). Minor species include animals such as zoo animals, ornamental fish, parrots, ferrets, and guinea pigs. Some animals of agricultural importance are also minor species including sheep, goats, catfish, game birds, and honey bees among others. Upon request by a sponsor and under the other requirements in section 573 of the FD&C Act (21 U.S.C. 360ccc–2), FDA may add a drug intended for use in a minor species or for a minor use in a major species to the Index. The Index can be found at <http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/>

MinorUseMinorSpecies/ucm125452.htm.

Currently the Affirmation of Compliance Code for submission of the NADA, CNADA, or MIF number is the Veterinary New Animal Drug Application Number “VNA”. The current Affirmation of Compliance Code for the ANADA number is the Veterinary Abbreviated New Animal Drug Application Number “VAN”.

c. Investigational new animal drugs. The proposed rule mandates that the investigational new animal drug (INAD) file number or the generic investigational new animal drug file (JINAD) number be submitted in ACE at the time of entry for articles that are subject to investigational new animal drug or generic investigational new animal drug applications under 21 CFR part 511. An investigational new animal drug is an animal drug that is used in a clinical investigation, or for tests in vitro or in animals only used for laboratory research purposes. An investigational new animal drug for which an INAD is in effect in accordance with part 511 is exempt from the premarket approval requirements that are otherwise applicable and may be shipped lawfully for the purpose of conducting clinical investigations of that drug (§ 511.1).

CVM issues a unique number that corresponds to each INAD and JINAD file that is established. Currently the Affirmation of Compliance Code for the INAD or JINAD is the Veterinary Investigational New Animal Drug Number “VIN”.

5. Medical Devices

A medical device is an article intended to either: (1) Diagnose a disease or condition or cure, mitigate, treat or prevent a disease or (2) affect the structure or any function of the body, and that does not achieve its primary intended purposes by chemical action or being metabolized (section 201(h) of the FD&C Act). The proposed rule covers only those medical devices intended for use in humans. Medical devices can be as simple as a tongue depressor or as complex as a robotic surgery device. FDA has issued rules to regulate medical devices that are intended to be introduced in U.S. commerce and these can be found at 21 CFR parts 800–900. The classification of a medical device under section 513 of the FD&C Act (21 U.S.C. 360c) determines, in part, the extent of FDA’s regulation of that medical device. There are currently 1700 generic groups of medical device types that are classified within 16 medical specialties (21 CFR parts 862–892). Class I devices

(approximately 780 medical devices) are considered to be low risk, class II devices (approximately 800 medical devices) are considered to be medium risk, and class III devices (approximately 100 medical devices) are considered to be high risk. Class III devices include certain medical devices that are life-supporting or life-sustaining, are for a use that is of substantial importance in preventing impairment of human health, or present a potential unreasonable risk of illness or injury (21 CFR 860.3(c)(3)). Because class III devices are considered to be high risk, most class III devices require premarket approval from FDA before they can be introduced into interstate commerce.

The proposed rule would make the following information for medical devices regulated by FDA’s Center for Devices and Radiological Health (CDRH) required submissions in ACE or any other CBP-authorized EDI system, at the time of entry. All of this information can currently be submitted in ACS.

a. Registration and listing. The proposed rule would 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. Any owner or operator of an establishment, not exempt under section 510(g) of the FD&C Act, that is engaged in the manufacture, preparation, propagation, compounding, or processing of a medical device intended for human use must register on an annual basis and submit listing information to FDA for those medical devices intended for commercial distribution (section 510 of the FD&C Act). Foreign establishments are required to designate a U.S. agent and submit the name, address, and telephone number of that agent as part of their registration under 21 CFR 807.40. Such establishments are also required to register and list the name and contact information, and registration number, if any has been assigned, of each known importer or any person who imports or offers to import the establishment’s medical devices into the United States (21 CFR 807.41).

A Foreign Exporter is required to register and list the medical devices it imports into the United States (section 510(i) of the FD&C Act; 21 CFR 807.20). FDA considers a foreign establishment that only exports medical devices to the United States to be engaged in the manufacture, preparation, propagation, compounding, or processing of a medical device which requires registration and listing (see Response to

Comment 5 in 77 FR 45927 at 45930, August 2, 2012).

When a registrant successfully completes the required registration process, a unique Registration Number is assigned by FDA. The current Affirmation of Compliance Codes for submission of the registration number of a Domestic Manufacturer is “DDM”; of a Foreign Manufacturer is “DEV”; and of a Foreign Exporter is “DFE.”

The information required to be submitted for each listed medical device, as enumerated in part 807, 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 a Device Listing Number for each medical device associated with the registration. While the Registration Number is publicly available, the Device Listing Number is not available to the public. The current Affirmation of Compliance Code for the Device Listing Number that must be submitted in ACE is “LST.” The requirements for registration and device listing are found in part 807.

Mandatory submission of the Registration and Device Listing Numbers in ACE at the time of entry serves as a safeguard against substandard and counterfeit medical devices entering the U.S. market. Medical devices manufactured for other countries may not be as safe and effective as medical devices made for the U.S. market. Additionally, medical devices from foreign manufacturers that were not initially intended for sale in the United States may not be adequately stored or maintained, which can affect package integrity, sterilization, and other issues relating to the medical device’s performance capabilities. Package labeling for these products may not comply with the requirements for distribution in the United States as the labeling may not be in English, may not contain adequate directions for use, and/or may not comply with other labeling requirements for the U.S. market. All of these issues can impact patient safety.

A medical device that is manufactured, prepared, propagated, compounded, or processed by an establishment that fails to register and/or that is not listed as required in section 510 of the FD&C Act is deemed misbranded (section 502(o) of the FD&C

Act). Medical devices that appear to be misbranded are subject to detention and refusal (section 801(a) of the FD&C Act).

b. *Investigational devices.* An investigational device is a medical device that is the object of a clinical investigation or research involving one or more subjects to determine the safety or effectiveness of a medical device (21 CFR 812.3(g) and (h)). An investigational device exemption (IDE) permits a medical device that otherwise would be required to be approved or cleared by us to be lawfully introduced into interstate commerce for the purpose of conducting investigations.

The IDE regulations (21 CFR part 812) describe three types of device studies: significant risk (SR), nonsignificant risk (NSR), and exempt studies. For a study determined to be SR, the sponsor must submit an IDE application to FDA for the investigational device and obtain the Agency’s approval before beginning the study (§ 812.20). A medical device used in an NSR study is considered by FDA to have an approved IDE, as long as the sponsor satisfies the requirements set forth in § 812.2(b). Devices used in exempt studies are not required to have an approved IDE.

The current Affirmation of Compliance Code for investigational devices is “IDE.” The proposed rule would require that an ACE filer submit in ACE at the time of entry, in the data field for the “IDE” code 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.

An investigational device that lacks a required IDE is deemed adulterated and misbranded (sections 501(f)(1) and 502(o) of the FD&C Act). Medical devices that appear to be adulterated and/or misbranded are subject to detention and refusal (section 801(a) of the FD&C Act).

c. *Premarket number.* In ACS, there are separate submissions for Premarket Approval and Premarket Notification Numbers. Under the proposed rule, there would be only one submission in ACE at the time of entry: Premarket Number “PM#.” The Premarket Number that would be a required submission in ACE at the time of entry is the following number/unique identifier that is issued by FDA:

- Premarket Approval Application (PMA) Number for those medical devices that have received pre-market approval under section 515 of the FD&C Act (21 U.S.C. 360e);

- Product Development Protocol (PDP) Number for those medical devices for which FDA has declared the PDP complete under section 515(f) of the FD&C Act;

- Humanitarian Device Exemption (HDE) Number for those medical devices for which an exemption has been granted under section 520(m) of the FD&C Act;

- Premarket Notification (PMN) Number is the 510(k) number for those medical devices that have received premarket clearance under section 510(k) of the FD&C Act (21 U.S.C. 360(k)); or

- De Novo (DEN) Number is the number for those medical devices that have received marketing authorization under section 513(f) of the FD&C Act.

This change from ACS should reduce the opportunity for filer error in ACE as the applicable Premarket Number, whether it is a PMA, PDP, HDE, PMN, or DEN Number, would be entered in the one data field rather than in ACS where a PMN Number could be erroneously entered in the field for a PMA Number.

The premarket approval pathway is used by the Agency to review and evaluate the safety and effectiveness of most class III devices. The PMA must include, among other things, descriptions of the methods used in, and the facilities and controls used for, the manufacture, processing, packing, storage, and, where appropriate, installation of the medical device (§ 814.20(b)). Premarket approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence that there is reasonable assurance of the medical device’s safety and effectiveness for its intended use(s). The PMA Number is the number issued by FDA upon the approval of a PMA.

Any person may submit to FDA a PDP with respect to a class III device that is required to have an approved PMA (section 515(f) of the FD&C Act). Under § 814.19, a class III device for which a PDP protocol has been declared completed by FDA is considered to have an approved PMA. The PDP Number is the number issued by FDA upon completion of the PDP.

A humanitarian use device (HUD) is a medical device that is intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year (§ 814.3(n)). A HDE is an exemption for a HUD from the effectiveness requirements of sections 514 and 515 of the FD&C Act, which is granted by FDA under section 520(m)(2)

of the FD&C Act. The HDE Number is issued by FDA upon approval of the exemption.

A PMN Number is the 510(k) number for those medical devices that have received premarket clearance from FDA based on a demonstration that the medical device to be marketed is substantially equivalent to a legally marketed predicate device that is not subject to premarket approval (section 510(k) of the FD&C Act; part 807).

If manufacturers have received an NSE determination on a 510(k) submission or determine that there is no legally marketed predicate device upon which to base a determination of substantial equivalence for their low to moderate risk medical device, an application for marketing authorization, known as a de novo request, may be submitted to FDA under section 513(f) of the FD&C Act. When FDA grants marketing authorization for a medical device through the de novo pathway, FDA issues a DEN Number for the medical device.

A medical device that is being imported or offered for import but lacks FDA approval or clearance, and is not otherwise exempt from such approval or clearance, is deemed adulterated and misbranded under sections 501(f)(1) and 502(o) of the FD&C Act. Medical devices that appear to be adulterated and/or misbranded are subject to detention and refusal (section 801(a) of the FD&C Act).

d. Component. The proposed rule would require an ACE filer to identify at the time of entry in ACE that the article being imported or offered for import is a component of a medical device that requires further processing or inclusion into a finished medical device. Component means any raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled medical device (21 CFR 820.3(c)). Finished medical device means any medical device or accessory to any medical device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized (§ 820.3(I)). We need this information to distinguish between a medical device component and a finished medical device that requires the submission of a "PM#." Components of a medical device may be subject to different statutory and regulatory requirements than finished medical devices so distinguishing between a component and a finished medical device (or accessory) is important in our ability to conduct an effective admissibility review. The current Affirmation of

Compliance Code for a component is "CPT."

e. Lead wire/patient cable. Electrode lead wires and patient cables intended for use with a medical device are required to meet the performance standard in 21 CFR 898.12, unless an exemption or variance is granted by FDA. Electrode lead wires and patient cables that are declared, purported or presented as being in conformity with § 898.12 but that are not, and do not have an exemption or variance, are deemed to be adulterated (section 501(e) of the FD&C Act). A medical device that is being imported or offered for import that appears to be adulterated is subject to detention and refusal (section 801(a) of the FD&C Act). For electrode lead wires and patient cables intended for use with a medical device, the proposed rule would require an ACE filer to submit an Affirmation of Compliance with the applicable Performance Standard for Electrode Lead Wires and Patient Cables (§ 898.12) in ACE at the time of entry. The current Affirmation of Compliance Code for electrode lead wires and patient cables intended for use with a medical device is "LWC."

f. Impact resistant lens. The frequency of eye injuries resulting from the shattering of ordinary crown glass lenses together with the consensus of the ophthalmic community that the number of eye injuries would be substantially reduced by the use of impact-resistant lenses in eyeglasses and sunglasses led to the issue of 21 CFR 801.410. 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 proposed rule would require submission at the time of entry in ACE of an Affirmation of Compliance with § 801.410. The current Affirmation of Compliance Code is "IRC."

g. Convenience kit. A convenience kit, assembled in kit form for the convenience of the purchaser or user, must be comprised of legally marketed medical devices. Convenience kits imported or offered for import have been found at times to contain recalled or unapproved medical devices. The proposed rule would 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."

h. Investigational new drug application number. We propose to require that the IND number be submitted in ACE at the time of entry for an article that is subject to an IND and that is a combination product consisting of at least one medical device and one investigational new drug where FDA's CDRH has been designated by FDA pursuant to 21 CFR 3.4 as the center with primary jurisdiction for the premarket review and regulation of the combination product. A combination product is defined in 21 CFR 3.2(e). CDRH may have primary jurisdiction over the following types of combination products with IND numbers: Investigational drug/device or investigational drug/device/biologic.

An investigational new drug is a new drug that is used in a clinical investigation (section 505(i) of the FD&C Act and § 312.3(b)). An investigational new drug for which an IND is in effect is exempt from the premarket approval requirements that are otherwise applicable and may be shipped lawfully for the purpose of conducting clinical investigations of that drug (part 312). Additionally, an investigational new drug for which an IND is not yet in effect may be shipped lawfully to an investigator named in the IND if the sponsor has received earlier FDA authorization to ship the drug (§ 312.40(c)(2)).

Currently the Affirmation of Compliance Code for submission of the IND number for a combination product that is subject to an IND consisting of at least one device and one investigational new drug, over which CDRH has been designated by FDA as the center with primary jurisdiction, is "IND".

We invite comments on the advantages, disadvantages, and feasibility of requiring an ACE filer to submit the IND number for these combination products in ACE at the time of entry. In particular, we invite 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.

6. Radiation-Emitting Electronic Products

FDA regulates radiation-emitting electronic products in order to protect the general public from hazardous and unnecessary exposure to radiation from electronic products. FDA has the statutory authority to regulate these products (Chapter 5, subchapter C of the FD&C Act). Our radiation safety regulations for manufacturers of

radiation-emitting electronic products can be found at 21 CFR parts 1000–1050.

Importers of radiation-emitting electronic products subject to an FDA performance standard are required to submit a written declaration on “Declaration of Products Subject to Radiation Control Standards,” Form FDA 2877 (19 CFR 12.91). Mandatory radiation safety performance standards established by FDA are enumerated in parts 1020 through 1050. The first section of each standard defines and describes the products subject to that standard. Table 1 of part 1002.1 contains a list of products followed by a reference to any applicable standards. A completed Form FDA 2877 is currently required to be submitted with the entry (19 CFR 12.91). In ACE or any other CBP-authorized EDI system, the declarations required in Form FDA 2877 must be submitted electronically at the time of entry for those radiation-emitting electronic products subject to the standards under parts 1020 through 1050.

Radiation-emitting electronic products that are being imported or offered for import that do not have the Form FDA 2877 declarations electronically submitted in ACE at the time of entry or that otherwise appear to be noncompliant with the applicable performance standard(s) may be detained and refused (section 536 of the FD&C Act).

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

FDA’s CBER regulates biological products under sections 351 and 361 of the PHS Act and various provisions of the FD&C Act. These products include blood and blood products (including certain kinds of devices), vaccines, allergenics, tissues, and cellular and gene therapies. CBER also regulates a number of drugs approved under section 505 of the FD&C Act, including plasma volume expanders, and drugs used in the collection and processing of blood components and human cellular products. Medical devices involved in the manufacture and administration of licensed blood, blood components, and cellular products and all HIV test kits used both to screen donor blood, blood components, and cellular products and to diagnose, treat, and monitor persons with HIV and AIDs, are also regulated by CBER. Also regulated by CBER are HCT/Ps, including those HCT/Ps that meet the criteria listed in § 1271.10(a) and that are therefore subject to regulation solely under section 361 of the PHS Act and part 1271.

Submission of the following information in ACE or any other CBP-authorized EDI system, at the time of entry would allow FDA to identify, appropriately categorize, and apply the applicable statutory and regulatory requirements to these CBER-regulated products. This information would enable us to more effectively and efficiently conduct admissibility review for these articles. 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.

a. *Product name.* This data element identifies the CBER-regulated article by the name commonly associated with that article such as 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. This information is currently collected in ACS but would become a required submission in ACE at the time of entry under the proposed rule.

For certain products, the established name, trade name, brand name, proper name, or product description is necessary to verify compliance with an FDA approval, licensing, or registration and listing requirement. A proper name is the name designated in a biologics license issued by FDA under section 351 of the PHS Act. If no established name, trade name, brand name, or proper name is available, a product description would be required to be submitted in ACE at the time of entry. For HCT/Ps regulated solely under section 361 of the PHS Act and the regulations in part 1271 (e.g. tendon, bone, cornea for transplantation) that do not have established names, trade names, brand names, or proper names, a description of the type of HCT/P that complies with § 1271.370 would be required.

b. *HCT/Ps 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)). FDA is authorized to make and enforce such regulations as are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States (section 361 of the PHS Act). Under that authority, we created a unified registration and listing system for establishments that manufacture HCT/

Ps. We also established donor-eligibility, current good tissue practice, and other procedures to prevent the introduction, transmission, and spread of communicable diseases by HCT/Ps.

Certain conditions provided under § 1271.420 apply to the importation of HCT/Ps regulated solely under section 361 of the PHS Act and part 1271. When an HCT/P meeting the criteria under § 1271.10(a) is offered for import, unless otherwise exempt, the importer of record must notify, either before or at the time of importation, the director of the FDA District Office 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, and must provide sufficient information for FDA to make an admissibility decision. Additionally, unless otherwise exempt, the HCT/P must be held intact by the importer or consignee, under conditions necessary to prevent transmission of communicable diseases, until we determine admissibility.

Most foreign manufacturers of HCT/Ps are required to register and submit a list of every HCT/P manufactured, except those exempt from registration under § 1271.15. Establishments that manufacture HCT/Ps that are regulated solely under the authority of section 361 of the PHS Act are required to register and list their HCT/Ps with CBER and to comply with the requirements of part 1271, whether or not the HCT/P enters into interstate commerce (§ 1271.1(b)(1)).

When an establishment successfully completes the required registration process, CBER assigns a unique registration number to that firm (see § 1271.27). 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, FDA is proposing to require the submission of that registration number in ACE at the time of entry. The list of registered firms and product listings are publicly available at <https://www.accessdata.fda.gov/scripts/cber/CFAppsPub/tiss/index.cfm>. The current Affirmation of Compliance Code for the HCT/P Registration Number is “HRN”.

For HCT/Ps regulated solely under section 361 of the PHS Act and the regulations in part 1271, FDA has established requirements in part 1271 such as applicable donor screening and testing, processing, and labeling, in order to prevent the introduction, transmission, and spread of communicable diseases by HCT/Ps. The proposed rule would 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".

c. *CBER-regulated licensed biological products.* A biological product is defined as a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings (section 351(i) of the PHS Act). The introduction or delivery for introduction into interstate commerce of any biological product, including certain devices, without a biologics license in effect for that specific product is prohibited (section 351(a)(1) of the PHS Act). The BLA is a request for authorization to introduce, or deliver for introduction, a biological product into interstate commerce. The licensing requirements and applicable standards for biological products are found in 21 CFR parts 600–680. CBER assigns a unique number to the original BLA or supplement and that serves as the Submission Tracking Number (STN).

Upon approval of the first BLA submitted by a manufacturer, CBER issues a Biologics License Number (BLN) to that manufacturer. A manufacturer may have several biological products with approved applications under one biologics license and each of the approved products will have its own STN.

For biological products being imported or offered for import that are subject to an approved BLA, the applicable BLN and/or STN would be a required submission in ACE at the time of entry. Currently the Affirmation of Compliance Code for submission of the BLN or STN in ACE is "BLN" or "STN". Failure to obtain an approved BLA as required under section 351 of the PHS Act subjects a biological product that is being imported or offered for import to detention and refusal under section 801(a)(3) of the FD&C Act.

d. *CBER-regulated human drugs.*

i. *Drug registration and listing.* The proposed rule would require that the Drug Registration Number be submitted in ACE at the time of entry, as explained earlier in the Human Drugs section, and this number would also be submitted for

those articles that are CBER-regulated drugs. Currently the Affirmation of Compliance Code for the submission of the Drug Registration Number is "REG".

The rule would also require the submission of the Drug Listing Number in ACE at the time of entry, as explained earlier in the Human Drugs section, and this number would also be submitted for those articles that are CBER-regulated drugs. The current Affirmation of Compliance Code for submission of the Drug Listing Number is "DLS".

We invite comments on the advantages, disadvantages, and feasibility of requiring an ACE filer to submit the Drug Listing Number for those articles that are CBER-regulated drugs. In particular, we invite comment on whether the submission by an ACE filer of this information will 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.

ii. *Drug application number.* In addition, the proposed rule would require that the number of the NDA or the number of the ANDA be submitted in ACE at the time of entry for those articles that are CBER-regulated drugs subject to an approved NDA or ANDA. Currently the Affirmation of Compliance Code for submission of the NDA or ANDA number in ACE is "DA".

iii. *Investigational new drug application number.* The proposed rule would require the number of the IND also be submitted in ACE at the time of entry for those CBER-regulated articles, including unapproved drugs and unlicensed biological products that are subject to an IND under section 505(i) of the FD&C Act. Currently the Affirmation of Compliance Code for submission of the IND Number is "IND".

e. *CBER-regulated medical devices.*

i. *Registration and listing number.* For those CBER-regulated medical devices that must be registered with FDA under part 807, the proposed rule would 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. The current Affirmation of Compliance Codes for submission of the registration number of a Domestic Manufacturer is "DDM"; of a Foreign Manufacturer is "DEV"; and of a Foreign Exporter is "DFE." For the Device Listing Number that would be required to be submitted in ACE at the time of entry, the current Affirmation of Compliance Code is "LST."

ii. *Premarket number.* For those CBER-regulated medical devices that require premarket approval or notification, the Premarket Number (PM#) would be required to be submitted in ACE at the time of entry. The Premarket Number would be the PMA Number for those medical devices that have received premarket approval under section 515 of the FD&C Act; the PDP Number for those medical devices for which FDA has declared the PDP complete under section 515(f) of the FD&C Act; the HDE Number for those medical devices for which an exemption has been granted for a humanitarian device under section 520(m) of the FD&C Act; the PMN Number for those medical devices that have received premarket clearance under section 510(k) of the FD&C Act; or the DEN Number for those medical devices that have received marketing authorization under section 513(f) of the FD&C Act. As explained earlier, under the proposed rule, there is only one Affirmation of Compliance Code that covers PMA, PDP, HDE, PMN and DEN Numbers: Premarket Number "PM#".

iii. *Components.* For those articles that are a component of a CBER-regulated medical device and that require further processing or inclusion into a CBER-regulated medical device, an affirmation that the article is such a component (CPT) would be required to be submitted in ACE at the time of entry. The current Affirmation of Compliance Code for a component is "CPT."

iv. *Investigational medical devices.* The current Affirmation of Compliance Code for investigational medical devices is "IDE." If the CBER-regulated device is an investigational device being imported or offered for import for use in an SR study which has been granted an exemption under section 520(g) of the FD&C Act, the number of the IDE would be required to be submitted in the data field for the "IDE" Code in ACE at the time of entry. If the investigational device is being imported or offered for import for use in an NSR or exempt study, as explained earlier in the Medical Devices section, "NSR" would be submitted in the data field for the "IDE" Code in ACE at the time of entry.

8. Tobacco Products

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) into law. The Tobacco Control Act granted FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and

to reduce tobacco use by minors. A “tobacco product” means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product) but does not include an article that is a drug, a device, or a combination product (section 201(rr) of the FD&C Act). Tobacco products are not limited to products containing tobacco, but also include components, parts, or accessories of tobacco products, whether they are sold for further manufacturing or for consumer use; e.g. cigarette rolling papers and filters are tobacco products, whether they are sold to consumers for use with roll-your-own tobacco or are sold for further manufacturing into a product sold to a consumer, such as a cigarette.

Importers are reminded that tobacco products imported or offered for import into the United States must comply with all the applicable requirements under the FD&C Act as amended by the Tobacco Control Act. For a tobacco product to be legally marketed in the United States, it must be grandfathered or a manufacturer generally must: (1) Have submitted a pre-market tobacco application (PMTA) and received a subsequent marketing authorization order under section 910(c)(1)(A)(i) of the FD&C Act (21 U.S.C. 387j(c)(1)(A)), or (2) have submitted a substantial equivalence (SE) report under section 905(j) of the FD&C Act (21 U.S.C. 387e(j)) and received a subsequent marketing authorization order, or (3) have been granted a request for an exemption from demonstrating substantial equivalence (EXE) under section 905(j)(3) or filed a report under section 905(j)(1)(A)(ii) of the FD&C Act and waited 90 days from submission of that report. CTP issues a Submission Tracking Number for a PMTA, SE., or EXE.

We recommend that ACE filers submit the optional data elements identifying the legal marketing status of the tobacco product, as described previously, in ACE or any other CBP-authorized EDI system, at the time of entry to help us efficiently evaluate the admissibility of a tobacco product being imported or offered for import.

a. *Brand name.* The proposed rule would require that the brand name for a tobacco product be submitted in ACE at the time of entry. This data element identifies a tobacco product by the name commonly associated with it: Brand name. Along with product code, the brand name will help us with screening

and targeting, to help determine which products to review manually. In addition, brand name may help FDA to determine if a tobacco product is adulterated under section 902 of the FD&C Act (21 U.S.C. 387b) or may be misbranded under section 903(a)(1) of the FD&C Act (21 U.S.C. 387c(a)(1)) or in violation of other provisions of the FD&C Act. Tobacco products that appear to be misbranded or adulterated are subject to detention and refusal (section 801 of the FD&C Act).

b. *Name and address of the ACE filer.* We are proposing 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. The name and address of ACE filers of imports that include a tobacco product would help to facilitate distribution by the Agency to ACE filers of materials related to the regulation and importation of tobacco products and otherwise communicate with the ACE filer.

We invite 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 invite 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 will 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.

9. Cosmetics

The FD&C Act defines “cosmetic” as articles intended to be rubbed, poured, sprinkled, sprayed on, introduced into, or otherwise applied to the human body for cleansing, beautifying, promoting attractiveness or altering the appearance and articles intended for use as a component of such articles (section 201(i) of the FD&C Act). The definition of “cosmetic,” however, does not include soap (see definition in 21 CFR 701.20).

FDA regulates cosmetic products. Although we do not have the legal authority to approve cosmetic products before they enter the market, we do approve color additives used in cosmetic products (except for coal tar hair dyes). However, under section 301(a) of the FD&C Act (21 U.S.C. 331(a)), cosmetic articles that are imported or offered for import cannot be lawfully marketed in interstate commerce if they are deemed to be

adulterated or misbranded, under sections 601 and 602 of the FD&C Act (21 U.S.C. 361 and 362).

The proposed rule would require the submission at the time of entry in ACE or any other CBP-authorized EDI system of only the general data elements under proposed § 1.72 for cosmetic articles being imported or offered for import into the United States.

D. Technical Amendments

1. Revisions to §§ 1.83 and 1005.2

We are proposing to revise §§ 1.83 and 1005.2 to update the legal references in those sections and to clarify the definition of “owner or consignee.” When section 801 of the FD&C Act was enacted, the term used to describe the person responsible for making entry of an imported product was “owner or consignee.” This term was the same term found in the relevant Customs statutes for the person required to make entry of imported merchandise. At the time section 801 of the FD&C Act was enacted, 19 U.S.C. 1483, 1484, and 1485, provided that the “consignee” was deemed to be the “owner” of imported merchandise and was required to make entry with Customs (now CBP). When FDA first issued §§ 1.83 and 1005.2 we defined “owner or consignee” as the term is used in section 801(a), (b), and (c) of the FD&C Act to be interchangeable with the terms in the relevant provisions of the Tariff Act of 1930. Therefore, we defined “owner or consignee” “for purposes of section 801(a), (b), and (c) of the FD&C Act as . . . the person who has the rights of a consignee under the provisions of section 1483, 1484, and 1495 of the Tariff Act of 1930, as amended (19 U.S.C. 1483, 1484, 1495).”

In 1983, the relevant provisions of the Tariff Act of 1930 were amended to change the designation of the person with the right to make entry. Section 1483 was repealed and the text of sections 1484 and 1485 was revised to provide that the person authorized to make entry is the “importer of record” who can be the owner, the purchaser, or a customs broker who is appropriately designated as such by the owner, purchaser, or consignee. FDA is now updating its regulations to bring the definition 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.” As a result, we are updating §§ 1.83 and 1005.2 to remove the reference to section 1483, which was repealed, and to reflect the amended language in

sections 1484 and 1485. This proposed rule will clarify that, for purposes of section 801(a), (b), and (c) of the FD&C Act, the term “owner or consignee” means the person eligible to make entry under sections 19 U.S.C. 1484 and 1485, namely, the “importer of record.”

2. Revisions to § 1.90

We are proposing revisions to § 1.90 to better reflect current practice of FDA and CBP regarding the issuance of notice of sampling to persons importing merchandise that FDA desires to sample. The current language of § 1.90 provides that FDA is to request that the collector of customs provide the notice of sampling. The proposed rule revises § 1.90 to allow FDA to provide this notice directly, which will normally happen through a secure electronic system. The proposed rule also updates “collector of customs” to “Customs and Border Protection” which is the Federal agency within the Department of Homeland Security that is primarily responsible for maintaining the integrity of the borders and ports of entry in the United States.

3. Revisions to § 1.94

We are proposing to revise § 1.94 to clarify that electronic notification can be provided to importers of merchandise when FDA has determined that an article being imported or offered for import may be subject to refusal of admission and/or administrative destruction. Section 1.94 states that FDA shall provide written notice in these circumstances that we currently implement by providing written notice by mail. FDA is proposing to revise this section to clarify that FDA can provide either written or electronic notification. In the case of electronic notification, the notice will usually be provided through a secure electronic system.

4. Revisions to § 1271.420

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, proposing to revise § 1271.420 to make clear that, unless otherwise exempt, importers of record importing or offering for import HCT/Ps meeting the criteria in § 1271.10(a) would be required to submit at the time of entry the applicable information under the proposed rule in ACE or any other CBP-authorized EDI system. Currently, unless they fall within an exception, importers of record for these products

are required to provide sufficient information for FDA to make an admissibility decision on these products (§ 1271.420(a)).

VI. Proposed Effective Date

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

VII. Economic Analysis of Impacts

A. Introduction

FDA has examined the impacts of the proposed 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 Agencies to assess all costs and benefits (both quantitative and qualitative) 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 proposed rule. We believe that this proposed rule may be a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The Agency tentatively concludes that this rule would not have a significant economic impact on a substantial number of small entities covered by this proposed rule, but the impacts are uncertain so we are explicitly seeking comment on the impacts.

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 proposing “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. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

B. Summary of Benefits and Costs of the Proposed Rule

FDA is proposing a rule that would require certain data elements material to imports admissibility determination into the United States be submitted to the FDA via ACE as part of an import entry. The proposed regulation would 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 would require that certain key data be submitted as a part of the import entry filing in the new ACE system. This rule proposes to make the submission of these data elements mandatory in ACE for each import entry line for the FDA-regulated commodities specified in the proposed rule for which entry requests are submitted electronically. The proposed 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 destruction, to allow for electronic notification by FDA. The rule also clarifies that importers of record of human cells, tissues and cellular and tissue-based products (HCT/Ps) that are regulated solely under section 361 of the Public Health Service Act and part 1271, unless exempted, would be required to submit the applicable data elements included in the proposed rule in ACE at the time of entry.

The estimated costs of this proposed rule—and the cost savings—stem from the mandatory information that would be submitted and collected under the ACE system. In the baseline scenario for our estimates of these costs, we treated ACS as the shell for the submission of the information but assumed that without the proposed FDA regulation, the information would be collected in ACE only if voluntarily provided by ACE filers like under the current ACS system (scenario 1, table 1). An alternative baseline is CBP implementation of ACE with the data elements for the entry of FDA-regulated products (scenario 2, table 1). Under this scenario, the benefits, costs, and cost savings estimated for the proposed rule would be the same but would be attributed to ACE’s full implementation. The incremental costs and cost savings of this proposed rule, should it become final, would be zero under this baseline (scenario 2, table 1). This scenario now

appears likely, with the transition to ACE well-underway and the ACE system scheduled to become the only CBP-authorized EDI system for the electronic filing of entries containing an FDA-regulated product this year.

Table 1 shows the total costs, cost savings, and other benefits of this proposed rule; the costs and cost savings are reported on an annualized basis using a 3 and a 7 percent discount rate over a 20-year time horizon. Table 1 shows that under scenario 2, the incremental effects of the proposed rule would be zero (\$0); the benefits, costs, and cost savings would still be incurred but would be attributed to the implementation of ACE by CBP. Under the alternative scenario 1 the costs, cost savings, and the benefits would be incurred and attributed to this rulemaking by FDA. Annualized over a 20-year horizon, the costs of complying with this regulation (scenario 1) are

between \$53 million and \$193 million per year with a 3 percent discount rate; these costs are between \$51 million and \$186 million per year with a 7 percent discount rate (table 1).

The total 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 for scenario 1 are estimated to range from \$3 million to \$89 million with a 3 percent discount rate; these partially quantifiable benefits are estimated to range from \$3 million to \$88 million with a 7 percent discount rate (table 1). Some of these cost savings to both the trade community and FDA that we are able to only partially quantify would arise from the reduced time of import entry request processing and potentially fewer and shorter product holds as a result of increased efficiency of FDA's imports admissibility process. Benefits,

in terms of cost savings, to both FDA and the industry that we are able to quantify would 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.

Other potential benefits that we are unable to quantify at this time would 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 would also arise because by revising certain sections of 21 CFR Chapter I, the Agency would provide more clarity to the industry about the overall process of importing FDA-regulated products.

TABLE 1—TOTAL ANNUALIZED COSTS AND BENEFITS OF THE PROPOSED RULE ¹

Discount rate	Total annualized costs	Total benefits	
		Cost savings	Other benefits (not quantified)
SCENARIO 1.—The benefits, the costs and cost savings are attributed to FDA regulation			
3 percent	Range \$53 million to \$193 million.	Range \$3 to \$89 million	More efficient use of FDA's internal resources; potentially fewer import recalls; reduced misbranding; reduction of counterfeit imports on the U.S. market; increased efficiency of the overall import process due to fewer errors because of a better defined <i>the owner or consignee</i> term and the clarifications related to notice of sampling, allowing for electronic notice of hearing on refusal of admission and notice of potential destruction of drugs.
7 percent	Range \$51 million to \$186 million.	Range \$3 million to \$88 million.	More efficient use of FDA's internal resources; potentially fewer import recalls; reduced misbranding; reduction of counterfeit imports on the U.S. market; increased efficiency of the overall import process due to fewer errors because of a better defined <i>the owner or consignee</i> term and the clarifications related to notice of sampling, allowing for electronic notice of hearing on refusal of admission and notice of potential destruction of drugs.
SCENARIO 2.—The benefits, costs, and cost savings estimated under SCENARIO 1 would still be incurred, but would be attributed to the implementation of ACE			
3 percent	\$0	\$0	\$0
7 percent	\$0	\$0	\$0

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

The Economic Analysis of Impacts of the proposed 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 proposed rule at <http://www.regulations.gov> (Docket No. FDA-2016-N-1487) and is also available on

FDA's Web site at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm> (Ref. 4). We invite comments on this analysis.

VIII. 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 impact on the human

environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by the OMB under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520). A

description of these provisions is given in the *Description* portion of this section with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Importer's Entry Notice (OMB Control Number 0910-0046).

Description of Respondents: The respondents to this collection of information are domestic and foreign "importers of record" of FDA-regulated articles being offered for import into the United States. An "importer of record" may be the owner or purchaser of the article being imported, 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 Preliminary Regulatory Impact Analysis (PRIA) for the proposed rule (Ref. 4), we have estimated there are about 59,292 owners or purchasers who seek to import FDA-regulated articles into the United States on an annual basis, and we have estimated that 97.7 percent of these owners or purchasers will use customs brokers to file their import entries in ACE, and the other 2.3 percent will file their import entries themselves. We estimate that there are a total of 4,010 filers, which includes the 1,364 owners or purchasers of the article who will file their own import entry in ACE (= 59,292 owners or purchasers of the article offered for import \times (100-97.7) percent).

Description: FDA is proposing to revise the information collection request (ICR) currently approved under OMB Control Number 0910-0046 to account for the provisions of the proposed rule that provide for collection of information from importers via ACE. This ICR (titled "Importer's Entry Notice") was most recently approved by

OMB on June 30, 2014, and received an expiration date of June 30, 2017. The currently approved collection of information allows the collection of several FDA data elements in ACS specific to FDA-regulated products in order for FDA to make import admissibility decisions. The ICR currently covers the following data elements for all FDA-regulated products: (1) FDA Product Code; (2) FDA country of production; (3) FDA manufacturer and shipper; and (4) ultimate consignee, as well as various affirmations of compliance specific to certain types of FDA-regulated products which an importer may submit to FDA to help facilitate FDA's review process. In making admissibility decisions FDA also uses additional entry information that CBP regulations require importers to submit (such as the entry number, importer of record, country of origin, etc.), but that information is collected under CBP statutes and regulations and ICRs managed by CBP (e.g., 19 U.S.C. 1484 and 1448(b), 19 CFR 142.3, 142.16, 142.22, and 142.24, and the associated ICR approved by OMB under OMB Control Number 1651-0024). The annual recordkeeping requirements for this collection are covered by the "Customs Modernization Act Recordkeeping Requirements" information collection approved by OMB under OMB Control Number 1651-0076.

The proposed rule and information collection would streamline FDA's admissibility review of FDA-regulated products, promote more effective utilization of industry and FDA resources, including electronic screening technology, and support FDA's ability to continue to meet its statutory responsibilities under the FD&C Act and the PHS Act. The information collection aspects of the proposed rule would specify the FDA-specific data elements that would be required as part of an import entry submitted in ACE for the FDA-regulated products covered by the proposed rule being imported or offered for import into the United States. Most data elements that would be collected in ACE under the proposed rule, with certain exceptions as explained below, are currently collected in ACS and approved for collection by OMB under OMB Control Number 0910-0046. Furthermore, under the proposed rule two of the data elements currently collected in ACS—FDA manufacturer and shipper and the ultimate consignee—would no longer be collected in ACE or any other CBP-authorized EDI system.

The authority to issue this proposed 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).

The information collection provisions of the proposed rule are in proposed §§ 1.72, 1.73, 1.74, 1.75, 1.76, 1.77, 1.78, 1.79, and 1.80. Proposed § 1.72 would require certain product identifying data elements and entity identifying data elements to be submitted in ACE at the time of entry for food as applicable, drugs, biological products, HCT/Ps, medical devices, radiation-emitting electronic products, cosmetics, and tobacco products. Proposed §§ 1.73 through 1.80 would 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. Proposed §§ 1.73, 1.74, 1.75, 1.76, 1.77, 1.78, 1.79, and 1.80 apply, respectively, to certain food products; 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.

All but four of the data elements that proposed subpart D would require filers to submit in ACE are currently collected in ACS and already approved for collection under OMB Control Number 0910-0046. Two of these four new data elements would be required by proposed § 1.72, which applies to certain foods as applicable, and drugs, biological products, HCT/Ps, medical devices, radiation-emitting electronic products, cosmetics, and tobacco products, and are the name, telephone number and email address for one of the persons related to the importation of the product, which may include the manufacturer, shipper, importer of record, or Deliver to Party, and a telephone number and email address for the importer of record, which we need to facilitate electronic notice under § 1.94 for certain FDA actions. The other two new data elements would be required by proposed § 1.79, which applies only to tobacco products, and are the name and address of the ACE filer and brand name of the tobacco product.

FDA concludes that the proposed data element of a telephone number and email address for the importer of record (which would be required by proposed § 1.72(b)(ii)) is not subject to the requirements of the PRA because the data element falls under an exception to

the term “information” under 5 CFR 1320.3(h)(1).

Under the currently approved ICR, the average time that it takes a filer to obtain and submit the four data elements and relevant affirmations of compliance information currently collected in ACS for all lines in an import entry is estimated at 8.4 minutes (0.14 hours). We did not receive any comments on the estimated burden enumerated in the ICR or its estimate of an average of 8.4 minutes per entry. This estimate of 8.4 minutes includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing, reviewing, and filing each entry. The estimate of 8.4 minutes is an *average* time across all import entries for FDA-regulated products and it accounts for the various realities of the entry filing process, such as the fact that the vast majority of lines (approximately 97 percent) are not unique lines, even unique lines in a single entry may contain redundant information, filers use sophisticated software that facilitates the entry filing process, and the time required per line may vary depending on the commodity and the specific characteristics of the product, manufacturer, etc.

Because two of the data elements that are currently collected in ACS—FDA manufacturer and shipper and the ultimate consignee—will not be collected in ACE or any other CBP-authorized EDI system under the proposed rule, we are reducing this estimate of 8.4 minutes to an estimate of 7.4 minutes.

In 2014, when OMB most recently approved this ICR, there was an average of 4.166 lines per entry for FDA-regulated products. We are converting the average of 7.4 minutes per entry into the average time per line. Therefore, the estimated time per import line that it takes a filer to submit the data elements that are currently approved under OMB Control Number 0910–0046 and would be submitted in ACE pursuant to the proposed rule, is approximately 1.776 minutes or 0.0296 hours (= 7.4 minutes / 4.166 lines).

The current estimated burden for this information collection approved under OMB Control Number 0910–0046, updated to account for the total number of FDA-regulated product lines submitted in ACS in 2015 (approximately 34 million lines) and annualized to account for estimated 3.3 percent increases in year two and three (for an annualized average of 35,133,681 lines in years one, two, and three), but not accounting for the estimated additional burden of the proposed rule for those lines that would be affected by

the proposed rule, is approximately 1,039,957 hours (= 35,133,681 lines × 0.0296 hours).

Using the estimates in the PRIA for the proposed rule, we have estimated that 33,988,154 import lines will be impacted by the proposed rule in the first year. We have also estimated that 975,460 import lines in the first year represent unique product-manufacturer combinations (2.87 percent of the 33,988,154 import lines). We have estimated that the number of impacted import lines will grow at an average rate of about 3.3 percent per year.

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

- Respondents would have to become aware of the rule requirements, which 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 would require an average of 30 minutes.

- Respondents would 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 would require about 4 minutes (0.0667 hours) per line on average. Because FDA has concluded that the proposed data element of a telephone number and email address for the importer of record (which would be required by proposed § 1.72(b)(ii)) is not subject to the requirements of the PRA, we have reduced this estimated time to 3.8 minutes for PRA purposes (approximately 0.0633 hours).

- Respondents would require an administrative worker to complete entry request for each import line and quality check using software that is connected to ACE, and that this would require about 2 minutes (0.033 hours) per line on average. Because FDA has concluded that the proposed data element of a telephone number and email address for the importer of record (which would be required by proposed § 1.72(b)(ii)) is not subject to the requirements of the PRA, we have reduced this estimated time to 1.8 minutes (0.03 hours) for PRA purposes.

- It would take respondents about 12.5 percent more time in the first year for an administrative worker to complete an entry request for each import line and quality check using software that is connected to ACE because they would have to adjust to the new system and data elements.

We have found based on our experience that filers no longer need to take a long time to familiarize themselves with changes in laws and rules relating to imports to determine how those changes would apply to an article being imported or offered for import, because much of these updates are now software-driven. For example, importers often rely on the electronic messages CBP sends to them notifying them of changes to data requirements. Furthermore, the proposed rule is fairly short, not complex, and does not require an inordinate number of data elements to be submitted in ACE for an FDA-regulated product.

Additionally, most of the general data elements that would be required by proposed § 1.72 of the proposed rule are currently collected in ACS, so filers should be very familiar with them. Almost all the data elements that would be required by the proposed rule in proposed §§ 1.73 through 1.80 have also been available for submission in ACS as Affirmations of Compliance and have been described in various FDA memoranda to the U.S. import trade community, so most filers should be generally familiar with them as well.

Entry filing processes have evolved technologically over time. The vast majority of filers currently rely on sophisticated software, which interacts with ACS and can be programmed to interact with ACE, to perform many of the tasks and functions that were previously performed manually, such as flagging mandatory data fields, providing quality checks, and record keeping. This increased reliance on sophisticated software has substantially reduced the entry filing burden. Importers also rely on the ACE system to flag mandatory data submissions and show an error message when an entry is rejected because a required data field is empty or is not completed in the required manner.

Our estimate of the increase in the reporting burden from the proposed rule primarily accounts for the proposed rule requiring submission of some data elements in ACE that are currently routinely collected submissions in ACS. We expect that some filers who were not submitting these data elements in ACS would have to change their submissions to comply with the proposed rule, if finalized. The annual reporting burden is higher in the first year than in years after because we expect most filers to adapt to submitting the required data they had not been submitting in ACS and to electronically store such data for future repeat lines.

Of note, FDA data shows that submission rates for the data elements

currently collected in ACS for many products are quite high. For example, for medical device lines, which make up approximately half of all import lines (based on 2014 and 2015 data) that would be affected by the proposed rule, approximately 98 percent are submitted with at least one affirmation of compliance, with an average of approximately three affirmations of compliance per line. Further, it appears that most medical device lines submitted in 2014 and 2015 through

ACS already include most of the information that would be required in ACE by the proposed rule. Additionally, cosmetic products, which make up approximately 8 percent of all import lines (based on 2014 and 2015 data) that would be affected by the proposed rule, would require no submission of information in ACE under the proposed rule other than the general data elements specified in proposed § 1.72.

As we noted previously, we have estimated that the number of import

lines affected by the proposed rule 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 proposed rule, we have annualized those 3.3 percent per year increases for 3 years. Accordingly, we expect the additional annual recurring reporting burden for the information collection that would result from this proposed rule, once finalized, to be as follows:

TABLE 2—ESTIMATED ADDITIONAL ANNUAL RECURRING REPORTING BURDEN ¹

Activity	No. of respondents	No. of responses per respondent (approximate)	Total annual responses	Average burden per response (in hours)	Total hours
Preparing the required information (applies to unique lines only).	59,292	17.01	1,008,337	0.0633 (3.8 minutes)	63,828
Quality checks and data submission into ACE	4,010	8,762	35,113,681	0.03 (1.8 minutes)	1,053,410
Total Hours	1,117,238

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 would result from this

proposed rule, if finalized, to be as follows:

TABLE 3.—ESTIMATED ONE TIME REPORTING BURDEN ¹

Activity	No. of respondents	No. of responses per respondent (approximate)	Total annual responses	Average burden per response (in hours)	Total hours
Review and familiarization with the rule	4,010	1	4,010	.5 (30 minutes)	2,005
First year adjusting to new requirements that would result in an average of 12.5 percent more time for quality checks and submission into ACE.	4,010	8,476	33,988,154	.00375 (0.225 minutes)	127,456
Total Hours	129,461

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 proposed rule, if finalized, would be 1,246,699 hours in the first year and 1,117,238 hours recurring after the first year.

As noted previously, the current estimated burden for this information collection, updated to account for the number of total FDA-regulated lines submitted to FDA in 2015 and an estimated 3.3 percent per year increase in lines in years two and three, but not accounting for the estimated additional burden of the proposed rule, is 1,039,957 hours. Therefore, we estimate that the total burden under this ICR, revised to include the estimated additional annual reporting burden under the proposed rule in addition to

the current annual reporting burden, would be 2,286,656 hours in the first year (= 1,039,957 current burden + 1,117,238 recurring burden + 129,461 one-time burden) and 2,157,195 hours annually after the first year (= 1,039,957 current burden + 1,117,238 recurring burden).

In compliance with the PRA (44 U.S.C. 3407(d)), the Agency has submitted the information collection provisions of this proposed rule to OMB for review. To ensure that comments on information collection are received, OMB recommends that written comments be faxed or emailed (see ADDRESSES). These requirements will not be effective until FDA obtains OMB approval. FDA will publish a notice

concerning OMB approval of these requirements in the **Federal Register**.

X. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that this proposed rule does not contain policies that would 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.

XI. References

The following references are on display in the Division of Dockets Management (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <http://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. Automated Commercial System and ABI CATAIR, CBP <http://www.cbp.gov/trade/acs/catair> (April 13, 2016).

2. FDA Guidance for Industry: *Submitting Form FDA 2541 (Food Canning Establishment Registration) and Forms FDA 2541d, FDA 2541e, FDA 2541f, and FDA 2541g (Food Process Filing Forms) to FDA in Electronic or Paper Format*. November 2015. <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm309376.htm>.

3. FDA Draft Guidance for Industry: *Implementation of the "Deemed to be a License" Provision of the Biologics Price Competition and Innovation Act of 2009*. March 2016. <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm490264.pdf>.

4. FDA, Full Disclosure of Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, and Unfunded Mandates Reform Act Analysis on Regulations on Electronic Submission of Import Data: Automated Commercial Environment Proposed Rule. 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, it is proposed that parts 1, 1005, and 1271 be amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

■ 1. The authority citation for part 1 continues 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, 342i, 343, 350c, 350d, 350e, 352, 355, 360b, 360ccc, 360ccc-1, 360ccc-2, 362, 371, 373, 374, 381, 382, 387, 387a, 387c, 393; 42 U.S.C. 216, 241, 243, 262, 264.

■ 2. Add subpart D, consisting of §§ 1.70 through 1.80, to read as follows:

Subpart D—Electronic Import Entries

Sec.

- 1.70 Scope.
- 1.71 Definitions.
- 1.72 Data elements that must be submitted in ACE for articles regulated by FDA.
- 1.73 Food.
- 1.74 Human drugs.
- 1.75 Animal drugs.
- 1.76 Medical devices.
- 1.77 Radiation-emitting electronic products.
- 1.78 Biological products, HCT/Ps, and related drugs and medical devices.
- 1.79 Tobacco products.
- 1.80 Cosmetics.

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 operated by the CBP, 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 the United States 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.

Combination product means a product comprised of two or more regulated components as defined in § 3.2(e) of this chapter.

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

Customs and Border Protection or *CBP* means the Federal Agency within the Department of Homeland Security that is primarily responsible for maintaining the integrity of the borders and ports of entry in 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.

Import line means each portion of an import entry that is listed as a separate item on an entry document.

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 as applicable, and 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 agree with the invoice description of the product.

(3) *FDA Value* which is the total value of the article(s) in an import entry or import line, rounded off to the nearest dollar, which must match the invoice value of those article(s).

(4) *FDA Quantity* which is the quantity of the article(s) in an import line delineated by packaging level, including the type of package from the largest packaging unit to the smallest packaging unit; the quantity of each packaging unit; and the volume and/or weight of each of the smallest of the packaging units.

(b) *Entity Identification Information*, (1) 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.

(2) Telephone and email address of the importer of record.

§ 1.73 Food.

(a) *Food*. The information specified in § 1.72(a)(3) must be submitted in ACE at the time of filing entry for food.

(b) *Food contact substances*. The information specified in § 1.72 must be submitted in ACE at the time of filing entry for food that is a food contact substance.

(c) *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.

(d) *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.

§ 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 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. 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 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 for animal drugs:

(a) *Registration and listing*. For a drug intended for animal use, the Drug Registration Number and the Drug Listing Number 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 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 pre-market 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.

(h) *Investigational new drug application number.* For a combination product consisting of at least one medical device and one 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, where the FDA Center for Devices and Radiological Health has been designated by FDA as the center with primary jurisdiction for the premarket review and regulation of the combination product, the number of the investigational new drug application.

§ 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 entry 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 and listing.* For a drug intended for human use, the Drug Registration Number and the Drug Listing Number. 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 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.

(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, an Affirmation of Compliance that identifies the device as being used in such a 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 the article that is a tobacco product being imported or offered for import.

(b) *Name and address* of the ACE filer for any entry that includes an article that is a tobacco product.

§ 1.80 Cosmetics.

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

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

§ 1.83 Definitions.

* * * * *

(a) The term *owner* or *consignee* means the person eligible to make entry under the provisions of sections 484 and 485 of the Tariff Act of 1930, as amended (19 U.S.C. 1484 and 1485), 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 on refusal of admission and the notice on 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 eligible to make entry under the provisions of sections 484 and 485 of the Tariff Act of 1930, as amended (19 U.S.C. 1484 and 1485), 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 United States Customs and Border Protection Agency as required in part 1, subpart D of this chapter, for FDA to make an admissibility decision.

* * * * *

Dated: June 28, 2016.

Leslie Kux,

Associate Commissioner for Policy, Food and Drug Administration.

In concurrence with FDA:

Dated: June 28, 2016.

Timothy E. Skud,

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

[FR Doc. 2016-15684 Filed 6-30-16; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG-2016-0451]

RIN 1625-AA00

Safety Zone; South Branch of the Chicago River and Chicago Sanitary and Ship Canal, Chicago, IL

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a temporary safety zone on the South Branch of the Chicago River and the Chicago Sanitary and Ship Canal, Chicago, IL. This action is necessary to protect spectators, participants, and vessels from the hazards associated with the Tough Cup event. This proposed rulemaking would prohibit persons and vessels from being in the safety zone unless authorized by the Captain of the Port Lake Michigan.

DATES: Comments and related material must be received by the Coast Guard on or before August 1, 2016.

ADDRESSES: You may submit comments identified by docket number USCG-2016-0451 using the Federal eRulemaking Portal at <http://www.regulations.gov>. See the “Public Participation and Request for Comments” portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email LT Lindsay Cook, Marine Safety Unit Chicago, U.S. Coast Guard; telephone (630) 986-2155, email Lindsay.N.Cook@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

- CFR Code of Federal Regulations
- DHS Department of Homeland Security
- FR Federal Register
- NPRM Notice of proposed rulemaking
- Pub. L. Public Law
- § Section
- U.S.C. United States Code