Importer's Entry Notice

OMB No. 0910-0046
Revision
RIN 0910-AH41

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The legal authority for 21 CFR Part 1 Subpart D and this associated collection of information 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).

The previously approved version of this Information Collection Request (ICR) accounts for the data elements collected by the U.S. Food and Drug Administration (FDA or "the Agency") from entry filers, primarily through the Automated Commercial System (ACS), for FDA regulated products imported or offered for import into the U.S.

FDA is revising this ICR to account for the additional collection of information in FDA's rule, "Submission of Food and Drug Administration Import Data in the Automated Commercial Environment" (also referred to hereinafter as the "rule"), which (in pertinent part) adds 21 CFR Part 1 Subpart D (See the Notice of Proposed Rulemaking (81 FR 43155 (July 1, 2016))). The rule requires that certain data elements, most of which were submitted in ACS, be submitted in the Automated Commercial Environment (ACE), which, as of July 23, 2016, is the sole electronic data interchange (EDI) authorized by U.S. Customs and Border Protection (CBP) for electronic submission of entry and entry summary information for FDA-regulated products being imported or offered for import into the U.S. ACS is no longer available for the electronic submission of entries that include FDA-regulated products.

Although primary responsibility for administering U.S. laws relating to imports is exercised by CBP, FDA is responsible for determining whether or not FDA-regulated articles are in compliance with the laws enforced by FDA and should be allowed to enter the U.S. The number of FDA-regulated products imported into the United States has grown steadily, from approximately 6 million import entry lines in 2002 to over 35 million import entry lines in 2015. The rule and this corresponding revision of this ICR will improve FDA's ability to effectively and efficiently conduct its initial admissibility review of the growing number of FDA-regulated import lines.

There are several important historical legislative and executive milestones which led to the development of ACE and the International Trade Data System (ITDS), FDA's proposal of 21 CFR Part 1 Subpart D, and this accompanying ICR revision request:

- Enacted in December of 1993, the Customs Modernization Act (Title VI of the North American Free Trade Agreement Implementation Act (Public Law 103-182)) mandated the development of ACE, the successor CBP-authorized EDI system to ACS. ACE is used by CBP to track, control, and process commercial goods imported into the U.S.

- Enacted in 2006, section 405 of the Security and Accountability for Every Port Act of 2006 (SAFE Port Act) (Public Law 109-347) mandated the development of ITDS to establish a single window through which industry would submit the data elements required for importation or exportation of certain commodities, with the goal of modernizing and simplifying the way in which participating government agencies (PGAs), including FDA, interact with importers. The SAFE Port Act requires that federal agencies participate in ITDS in order to obtain data for imported and exported goods.

- On February 19, 2014, President Obama issued an Executive Order, *Streamlining the Export/Import Process for America's Businesses* (EO 13659), requiring that (in pertinent part) by December 31, 2016, ITDS and ACE be fully implemented, with ACE serving as the "single window" for electronic submission of data elements for import of goods into the U.S.

- In the Federal Register on May 23, 2016 (81 FR 32339), CBP announced that, effective July 23, 2016, ACE is the sole CBP-authorized EDI system for electronic entry and entry summary filings for merchandise subject to the import requirements of FDA. These entries can no longer be submitted in ACS.

When shipments of goods are being imported or offered for import into the United States they must be "entered," at one of the CBP ports. The term "import entry," or "entry," refers to the information or documentation for a shipment that a filer must submit in ACE. An import entry line (or "line") is each portion of an entry that is listed as a separate item on an entry submission. CBP requires importers to submit entry line information, such as the entry number, importer of record, country of origin, product description, etc., for all merchandise imported into the U.S. unless specifically exempt.

Before this rule, when an electronic import entry contained products regulated by FDA, CBP collected four data elements in ACS to assist FDA in its admissibility review, specifically: (1) the complete FDA Product Code; (2) FDA Country of Production; (3) FDA manufacturer and shipper; and (4) the ultimate consignee. For these lines, filers also had the option of submitting any applicable FDA Affirmations of Compliance which related to certain statutory and regulatory requirements for the various commodities regulated by FDA. This information assists FDA in potentially expediting our initial screening for admissibility as well as any further review of the entry for admissibility.

After the entry filer submits the entry information in ACE, CBP electronically transmits that information to FDA. Because CBP relays the information to FDA electronically, generally the entry filer only needs to submit the entry information once provided the information is accurate.

Import entry lines that include FDA-regulated products are electronically screened in FDA's Operational and Administrative System for Import Support (OASIS) against criteria developed by FDA. 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 by evaluating the entry information to determine potential risks associated with each entry line. OASIS expedites the clearance of FDA-regulated products that present a low public health risk, but only if the importer of record provides accurate, relevant, and complete entry information that will assist FDA in determining admissibility. If the FDA electronic review determines that further evaluation by FDA is warranted, FDA import entry review personnel will manually review the entry information and may request additional information to make an admissibility determination and/or may examine or sample the FDA-regulated product.

This ICR relates to provisions of the rule that specify the data elements that FDA requires as part of an import entry submitted in ACE at the time of entry, for FDA-regulated products being imported or offered for import into the U.S. Most of these data elements, with certain exceptions as explained below, were collected previously (primarily through ACS) and accounted for by the previously approved ICR under OMB Control Number 0910-0046. Two of the data elements previously collected by CBP to assist FDA in its admissibility review (FDA manufacturer and shipper, and ultimate consignee) and accounted for under the previously approved ICR under OMB Control Number 0910-0046 are not required by the rule.

2. Purpose and Use of the Information Collection

This collection of information would require the submission in ACE of certain information, pursuant to the rule, for FDA-regulated products being imported or offered for import into the United States. The rule requires entry filers to submit this information in ACE each time an entry is electronically submitted for an FDA-regulated product. As noted above, this requested revision to the approved ICR will allow FDA to gather important and useful information about FDA-regulated products being imported or offered for import into the U.S., including data elements that were not collected in ACS. The collected information is used by FDA to initially screen and review FDA-regulated products being imported or offered for import into the U.S. for admissibility in order to prevent violative FDA-regulated products from entering the U.S.

3. Use of Improved Information Technology and Burden Reduction

21 CFR Part 1 Subpart D and the implementation of ACE/ITDS will build upon the automation successes of ACS. With the implementation of ACE, automated "May Proceed" determinations by FDA are expected to increase, and the international trade community will be able to more easily and efficiently import compliant FDA-regulated products into the U.S.

Based on previous ACS usage, FDA estimates that at least 96% of respondents will use ACE to electronically submit the information collected by this ICR.

Automated systems and associated electronic data storage of data have also been of great value to FDA personnel responsible for planning and delegating imports work, e.g., determining what FDA-regulated products and quantities are arriving at which ports, from which manufacturers, and from what countries, etc., and what products to physically examine and sample. FDA

expects the collection of information required by the rule and the improved information technology capabilities of ACE to increase this value to FDA.

4. Efforts to Identify Duplication and Use of Similar Information

FDA has collaborated extensively with CBP to make sure that the information collection of 21 CFR Part 1 Subpart D does not duplicate what is required by CBP or other PGAs.

Because CBP relays the entry data to FDA using the ABI/ACE electronic interface, an importer or entry filer needs to submit the information required by the rule only once, provided that the information is accurate.

5. Impact on Small Businesses or Other Small Entities

The information provided by filers pursuant to 21 CFR Part 1 Subpart D should not impose any undue burden on small businesses or other small entities.

As discussed the Regulatory Impact Analysis (RIA) for the rule, FDA estimates that 40,452 out of the 41,703 importers are small businesses and that 3,630 out of the 3,667 entry filers are small businesses. As also discussed in the RIA, the rule will affect small businesses and larger businesses in a very similar manner. The total annual burden per respondent should generally scale linearly with the annual number of entry lines that include FDA-regulated products and that number should generally scale linearly in accordance with the size of the respondent's business.

Furthermore, if needed, any filer can obtain assistance from their local FDA district, or from an FDA ACE "help desk."

6. Consequences of Collecting the Information Less Frequently

Respondents to this data collection are expected to respond occasionally – i.e., when imported shipments arrive or are due to arrive to the United States. Information must be submitted before or at the time goods arrive in the U.S. to enable FDA to determine if the product will be allowed to proceed into U.S. commerce immediately, or should be held pending further FDA review.

Because of the very large number of FDA-regulated products imported to the U.S. each year, FDA cannot physically examine every FDA-regulated article. Therefore, it is essential for FDA to receive information about every FDA-regulated article being imported or offered for import into the United States so FDA may remotely and electronically review the information to strategically focus FDA's resources on which articles FDA should admit without further review, which articles to detain without physical examination, and which articles to allocate further resources to, for example, by physically examining and/or sampling an article.

If the information were to be submitted on a less frequent basis, FDA could not adequately meet its statutory responsibilities to regulate imported products falling under FDA's jurisdiction, nor could it prevent those FDA-regulated products that potentially present a public health risk from entering the U.S. market. In turn, this lack of information could have an adverse effect on the American population, who is the final purchaser and consumer of these products.

This requested revision of the previously approved information collection request is vital for FDA to continue to prevent the importation of violative FDA-regulated products in a rapidly expanding, complex, and demanding international trade environment. If FDA were not able to collect the FDA-specific data elements in ACE under the rule, FDA's ability to determine the risk level of imported FDA-regulated products would be severely hampered. Coupled with the data elements required by CBP and shared with FDA, the required data elements in the rule are the key data/information that would most assist the Agency in making our initial admissibility determinations. By requiring certain data elements to be submitted in ACE at the time of filing entry, FDA expects that the number of import entries of FDA-regulated products that may receive an automated "May Proceed" determination from FDA will increase. This will allow FDA to more effectively focus its limited resources on those FDA-regulated products being imported or offered for import that may be associated with a higher public health risk.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

A respondent submits the information for this data collection in ACE at the time of filing entry each time the respondent imports or offers for import an FDA-regulated product to the U.S. This information is then electronically transmitted by CBP to FDA.

With regard to record retention, CBP regulation 19 CFR 163.4(a) requires filers to retain all entry documents for five years after the date of entry.

Although respondents may submit proprietary, trade secret, or other confidential information in response to this ICR; FDA, CBP, ACE, and ITDS have systems and procedures to protect the information's confidentiality in accordance with applicable law.

FDA reviews the FDA-required information submitted in ACE and conducts filer evaluations to make certain that accurate information is being transmitted by filers.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

As required by section 3506(c)(2)(B) of the Paperwork Reduction Act of 1995 (PRA), FDA provided an opportunity for public comment on the information collection requirements of the proposed rule published in the Federal Register at 81 FR 43155 (July 1, 2016).

Although FDA did not receive any comments specifically relating to the PRA, FDA did receive several comments relating to the rule and the RIA. We have revised our information collection burden estimates, as appropriate, to reflect revisions we made to the proposed rule and the RIA.

In developing and finalizing the rule and this associated ICR, HHS/FDA has also consulted extensively with appropriate departments and agencies such as CBP, the Department of Homeland Security, and the Department of the Treasury.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift was provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

No assurance of confidentiality has been provided except as generally provided for by 21 CFR 20.61.

11. Justification for Sensitive Questions

There are no questions asked of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Burden Estimate

FDA is revising the ICR approved under OMB Control Number 0910-0046 to adjust for FDA's previous underestimates of increases in the number of import lines containing FDA-regulated products, to adjust the ICR to account for collection of intended use information that had been previously unaccounted for, and to account for the provisions of 21 CFR Part 1 Subpart D that provide for additional collection of information from importers and entry filers via ACE. FDA has estimated that under the rule, more information will be collected in ACE than was collected previously in ACS, primarily because the rule will require submission of certain data elements in ACE that were optional submissions in ACS.

This collection of information through ACE should substantially reduce the number of entries presented to FDA that contain inaccurate or incomplete information, and in turn, reduce delays that occur when FDA reviewers have to either manually search for the missing information in FDA data systems or request follow-up documentation. In ACE, the average time for OASIS to process an import entry of an FDA-regulated product and issue an automated "May Proceed" has been reduced by approximately 75% from the time required to perform that same function when ACS was the sole CBP-authorized EDI system and, similarly, the time to process a manual "May Proceed" has been reduced by approximately 93%. Further, FDA expects that the number of automated "May Proceed" determinations by FDA in ACE will increase over the number of these determinations in ACS.

Various import entry related information collections are accounted for by other OMB-approved ICRs, so this ICR does not account for those collections. Specifically:

- In making admissibility decisions, FDA also uses entry information required by CBP (such as the entry number, importer of record, manufacturer, shipper, etc.), but that information is collected pursuant to 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 primary respondents to this collection of information are domestic and foreign importers of FDA-regulated articles being imported or offered for import into the United States and entry filers who submit import entries on behalf of these importers. An importer of record may be the owner or purchaser of the article being imported or offered for import, or a customs broker

licensed by CBP under 19 U.S.C. 1641 who has been designated by the owner, purchaser, or consignee to file the import entry. There is only one importer of record per entry.

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

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

Of the data elements that the rule requires ACE filers to submit in ACE at the time of entry, all except for four were previously collected from entry filers in ACS (as either required or optional submissions depending on the data element) and have been accounted for by the previously approved information collection under OMB Control Number 0910-0046. One of those four data elements, intended use information, had been collected from entry filers but not accounted for under an OMB approved FDA information collection. Under the rule, intended use information is collected in ACE in the form of an intended use code (IUC), pursuant to section 21 CFR 1.72. In ACS, FDA used the information, submitted in a free text format, in the CBP-required product description field to ascertain the intended use of the article being imported or offered for import into the U.S.

The rule also provides for the collection of three data elements to be collected in ACE that are new, i.e., we did not previously collect this information from entry filers in ACS. One of the three new data elements is required by 21 CFR 1.72, applicable to food contact substances, drugs, biological products, HCT/Ps, medical devices, radiation-emitting electronic products, cosmetics, and tobacco products, is the telephone and email address for the importer of record which will help to facilitate electronic notices provided by FDA under 21 CFR § 1.94 for certain FDA actions. One of the other two new data elements is required by 21 CFR 1.78, which applies only to biological products, HCT/Ps, and related drugs and medical devices, is the product name, and the other required by 21 CFR 1.79, which applies only to tobacco products, is the brand name of the tobacco product.

Under the previously approved ICR, OMB Control Number 0910-0046, the average time estimated for a filer to obtain and submit the aforementioned four data elements collected by CBP to assist FDA in its admissibility review and the optional Affirmations of Compliance in ACS for all lines in an entry was estimated at 8.4 minutes (0.14 hours). This estimate of 8.4 minutes per entry included 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 was 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%) are not unique lines, that 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 were collected in ACS and accounted for by the previously approved ICR under OMB Control Number 0910-0046 –FDA manufacturer/shipper and the ultimate consignee– will not be collected by FDA in ACE, FDA is reducing the previous estimate of 8.4 minutes to an estimate of 7.4 minutes to account for the collection of information in ACS that will also be collected in ACE.

To correspond with the RIA methodology, FDA is converting the average of 7.4 minutes per entry into an average time per line. In 2014, when OMB most recently approved the ICR under OMB Control Number 0910-0046, the average number of lines per entry containing an FDA-regulated product was approximately 4.16575. FDA therefore estimates that it takes a filer approximately 1.776 minutes per line (= 7.4 minutes divided by 4.16575 lines, rounded to four significant digits), approximately 0.0296 hours, to submit the data elements in ACE required under the rule that were previously submitted in ACS and approved under OMB Control Number 0910-0046.

As noted previously, filers could submit information in ACS about the intended use of a product as free text in the CBP-required product description data field. This intended use information could be used by FDA to assist in our determination of admissibility of the article. The collection of this intended use information for FDA's use was not accounted for under the previous versions of the FDA ICRs approved by OMB because the product description data element was required by CBP. Intended use information is collected in ACE in the form of IUCs, pursuant to §1.72 of the rule, to assist FDA in its admissibility review of an FDA-regulated article being imported or offered for import into the U.S. Accepting intended use information in the form of a code, rather than in the form of a free text description in the CBP-required product description field, will standardize and streamline filers' submissions of intended use information and facilitate an effective and efficient use of the intended use information by FDA.

FDA is requesting to add the reporting burden of determining and inputting the IUC to the FDA ICR under OMB Control Number 0910-0046. These IUCs are approved and published by CBP in Appendix R to the CATAIR. Although there are a number of IUCs in the CATAIR applicable to FDA-regulated products, only one IUC is submitted per import entry line. FDA has estimated,

pursuant to the below discussion, that the reporting burden of determining and entering the appropriate IUC information for each import line is, on average, an additional 15.0 seconds.

As indicated above, this estimate of 15.0 additional seconds to determine and input the appropriate IUC into ACE (via a selection menu) is an *average* time across all import lines 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 FDA-regulated lines (approximately 97.8%) are not unique lines. In other words, approximately 44 out of every 45 FDA-regulated entry lines are repeats of a unique line. FDA has estimated that for a unique line, it will take a filer 45 seconds to determine the appropriate IUC (e.g., reviewing instructions and gathering and maintaining the data needed). 45 seconds divided by 45 lines is and average of 1.0 second. FDA also estimates that for each unique and non-unique line it will take a filer, on average, 14 seconds to complete, review, and input the appropriate IUC. Therefore, FDA has estimated that, on average, the reporting burden of determining and entering the IUC data element for each line is 15.0 seconds (1.0 seconds + 14 seconds), which is 0.25 minutes.

FDA has therefore estimated the total burden to submit the data elements that were previously submitted in ACS and that will be submitted in ACE pursuant to the rule is 2.026 minutes (1.776 minutes + 0.25 minutes), which is approximately 0.03377 hours (rounded to nearest hundred thousandths place).

FDA is requesting an adjustment of the existing estimated burden for this information collection approved under OMB Control Number 0910-0046 to account for submission of intended use information that was previously unaccounted for in the FDA ICR and to account for an increase in FDA-regulated import lines, including increases in FDA-regulated import entries/lines that FDA had underestimated in several previous versions of the ICR approved under OMB 0910-0046. The total number of FDA-regulated product lines submitted in ACS in 2015 (approximately 34 million lines), annualized to account for estimated 3.3% increases in the number of import lines in year two and three, equals an annualized average of 35,133,681 lines in years one, two, and three. Pursuant to the RIA, FDA is also adjusting the number of filers from 3,736 to 3,667. Therefore, the adjusted hourly burden, without yet accounting for the additional burden of the rule, is approximately 1,186,464 hours per year, calculated as follows:

Table 1 – Estimated Existing Burden (after adjustment)

Activity	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total hours
Reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing, reviewing, and filing each entry	3,667	9,581	35,133,681	0.03377 hours (2.026 minutes)	1,186,464

FDA has used the relevant assumptions and estimates in the RIA for this rule, specifically those for Option 1 (the option which reflects the rule), to estimate the additional annual reporting burden pursuant to the rule.

Using the estimates in the RIA for the rule, FDA has estimated that the rule will impact 23,119,465 import lines in the first year. The rule will not impact import lines of foods other than acidified foods, low-acid canned foods, and food contact substances. FDA has also estimated that 504,768 of the impacted import lines in the first year represent unique product-manufacturer combinations. FDA has 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 of the RIA (Option 1) for the rule that affect FDA's estimate of the additional annual reporting burden are:

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

- Respondents (owners or purchasers) will require an administrative worker to locate, gather, and prepare the additional information required by this rule for each unique product-manufacturer import line; and this will require on average about 2.333 minutes (0.03889 hours) per line.

- Respondents (ACE filers) will require an administrative worker to submit the applicable data elements required in the final rule and respondents (ACE filers) may also require an owner or manager to check if the information is correct, or alternatively, require the administrative worker to quality check their submission using software that is connected to ACE. This will require about 1.166667 minutes (approximately 0.01944 hours) per line on average.

- It will take respondents about 25 percent more time in the first year for an administrative worker to complete each import line and quality check the information, because the respondent will have to adjust to the new system and data elements.

FDA expects that some filers who were not submitting the optional data elements previously will have to change their practices to comply with the rule. Notably, the submission rates of Affirmations of Compliance in ACS for some commodities were quite high. For example, in 2015 approximately 98% of medical device lines had at least one Affirmation of Compliance submitted in ACS. Based on 2014 and 2015 data, FDA estimates that medical device lines will make up about seventy percent of all import lines that will be impacted by the rule. On the other hand, for example, only 24% of animal drug import lines had at least one of the Affirmations of Compliance, although, based on 2014 and 2015 data, FDA estimates that animal drugs will make up less than .5% of all import lines that will be affected by the rule.

As noted above and explained in further detail in the RIA, FDA has estimated that the number of import lines affected by the 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 rule, FDA has annualized those 3.3 percent per year increases for three years.

In accordance with the above discussion, FDA expects the additional annual recurring reporting burden for the information collection that will result from this rule, once finalized, to be as follows:

Table 2.--Estimated Additional Annual Recurring Reporting Burden

Activity	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Preparing the required information (applies to unique lines only)	41,703	12.5	521,609	0. 0.03889 (2.333 minutes)	20,285
Quality checks and data submission into ACE	3,667	6,515	23,890,800	0. 01944 (1.1667 minutes)	464,543
Total Hours…..…..	……	……	……..	……...	484,828

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

Table 3.--Estimated One Time Reporting Burden

Activity	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Review and familiarization with the rule	3,667	1	3,667	0.5 (30 minutes)	1,834
First year adjusting to new requirements that will result in an average of 25 percent more time for quality checks and submission into ACE	3,667	6,305	23,119,465	0.00486 (0.29 minutes)	112,386
Total Hours….	……	……	……..	……...	114,220

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

As noted above, the adjusted estimated existing burden for this information collection, not yet accounting for the estimated additional burden of the rule, is 1,186,464 hours. FDA has estimated that the total burden under this ICR, revised to include the estimated additional annual reporting burden pursuant to the rule in addition to the adjusted existing annual reporting burden,

will be 1,785,512 hours in the first year (=1,186,464 existing burden hours + 484,828 recurring hours + 114,220 one-time hours) and 1,671,292 hours annually after the first year (= 1,186,464 existing burden hours + 484,828 recurring hours). This averages to an annual burden of 1,709,365 hours over the next three years of the approval of this ICR.

12b. Annualized Cost Burden Estimate

As discussed in section 12a above, FDA is adjusting the estimated existing burden for this information collection approved under OMB Control Number 0910-0046 to 1,709,365. The previously approved ICR uses an hourly wage rate of a GS-10 step 5 federal employee as a proxy to estimate the average hourly wage of all respondents across all activities. However, in accordance with the methodology used by the RIA for the rule, FDA is using a labor cost of $74.91 (= (114.88 + 34.94) / 2), which is the average between the cost for a general and operations manager and the cost for an administration worker, and includes overhead costs and benefits. Accordingly, FDA is adjusting the annualized cost burden estimate of this ICR – without yet accounting for the additional burden of the rule– to $88,878,018.

Table 4.--Adjusted Estimated Existing Burden, Not Accounting for the Rule

Type of Respondent	Total Burden hours	Hourly Wage Rate	Total Respondent Costs
Filer	1,709,365	$74.91	$128,048,532

The costs of the additional information collection pursuant to the rule are directly related to the time it will take respondents to perform the activities described in section 12a tables 1 and 2 above and the hourly wage rate of the particular respondent. Some activities will be recurring (preparing the required information for unique lines, and quality checking data and submitting the data into ACE) and other activities will occur one time (review and familiarization with the rule, and the 25 percent more time required for quality checks and submission into ACE in the first year). As also noted above in section 12a, FDA has estimated that the number of impacted import lines will grow at an average rate of about 3.3 percent per year, and FDA has annualized those increases over years one, two, and three.

In accordance with the RIA for the rule:

- The recurring activity of preparing the required information for unique lines will be performed by an administrative worker at a total average hourly wage rate of $34.94, which includes overhead costs and benefits.
- The recurring activity of quality checks and data submission into ACE will be performed by a combination of operations managers and administrative workers at a total average hourly wage rate of $73.43, which includes overhead costs and benefits.
- The one-time activity of review and familiarization with the rule will be performed by operations managers at an average hourly wage rate of $114.88, which includes overhead costs and benefits.
- The 25 percent additional time required for quality checks and submission into ACE in the first year affects only the activity of quality checks and data submission into ACE, which is performed by a combination of operations managers and administrative workers at a total average hourly wage rate of $73.43, which includes overhead costs and benefits.

Accordingly, FDA estimates the additional annualized cost burden estimate under this ICR pursuant to the rule (not yet accounting for the adjusted existing burden) will be $43,283,344 in the first year ($34,820,150 recurring cost + $8,463,194 one-time cost) and $34,820,150 annually recurring thereafter:

Table 5.--Estimated Annual Recurring Cost Burden Pursuant to the Rule

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Preparing the required information (applies to unique lines only)	20,285	$34.94	$708,758
Quality checks and data submission into ACE	464,543	$73.43	$34,111,392
Total			$34,820,150

Table 6.--Estimated One-Time Cost Burden Pursuant to the Rule

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Review and familiarization with the rule	1,834	$114.88	$210,690
First year adjusting to new requirements that will result in an average of 12.5 percent more time for quality checks and submission into ACE	112,386	$73.43	$8,252,504
Total			$8,463,194

When the adjusted existing annualized cost burden estimate ($88,878,018) and the additional annualized cost burden estimate pursuant to the rule are aggregated, FDA estimates that the total revised annualized cost burden estimate under this ICR will be $132,161,362 in the first year ($88,878,018 existing cost + $34,820,150 additional recurring costs + $8,463,194 additional one-time cost) and $123,698,168 annually thereafter ($88,878,018 existing cost + $34,820,150 additional recurring costs).

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection. Because the costs of updating the existing software or purchasing new software is attributed to general use of the ACE system for making electronic import entries, FDA does not account for those costs in this ICR.

14. Annualized Cost to the Federal Government

The previously approved version of this ICR estimates the average salary of an FDA import entry reviewer to be GS-10 as a base, and when step and locality pay are considered, to be $66,335 per year. The previously approved version of this ICR also estimates that 155 Full Time Equivalents (FTEs) are required to review the FDA-specific information on importers' entry notices. FDA does not expect the number of FTEs that are required to review importers' entry notices to change under the rule. However, in accordance with the methodology used by the RIA

for the rule, FDA is instead using $250,000 as the annual cost of one FDA employee, and that accounts for overhead costs and benefits.

Accordingly, FDA is adjusting its estimate of the annualized cost to the federal government to $38,750,000 per year (=$250,000 * 155 FTEs).

15. Explanation for Program Changes or Adjustments

As discussed in greater detail above, FDA is requesting OMB's approval to revise this ICR to account for additional collection of information provisions in FDA's rule that adds 21 CFR Part 1 Subpart D and to account for several adjustments:

- FDA is adjusting the existing estimated burden previously approved under OMB 0910-0046 (not yet accounting for the additional burden of the rule) from 528,102 hours to 1,186,464 hours, which is an adjustment increase of 658,362 hours, to account for an increase in FDA-regulated import lines, to account for the collection of intended use information in ACE as IUCs in the new rule, and to correct for FDA previous underestimates of the increases in the number of FDA-regulated entries for several past iterations of this ICR. Furthermore, this ICR has converted the reporting burden per entry to the reporting burden per line, and the number of FDA-regulated lines per FDA-regulated entry has increased over the past few years.

- As explained in detail above, FDA is requesting a program change increase of 599,048 hours in the first year and 484,820 hours recurring after the first year to account for the additional collection of information provisions in 21 CFR Part 1 Subpart D added by the rule.

16. Plans for Tabulation and Publication and Project Time Schedule

No tabulation of the data is planned or anticipated.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA is not seeking approval to exempt display of the OMB approval date on any documents that are associated with this information collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.