Importer's Entry Notice

OMB No. 0910-0046
Revision
SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The legal authority for proposed 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 currently approved version of this Information Collection Request (ICR) accounts for the data elements currently collected in the Automated Commercial System (ACS) from importers about products regulated by the U.S. Food and Drug Administration (FDA, or "the Agency") that are being imported or offered for import into the U.S.

FDA is revising this ICR to account for the additional collections of information in FDA's proposed rule, "Submission of Food and Drug Administration Import Data in the Automated Commercial Environment" which would (in pertinent part) add 21 CFR Part 1 Subpart D (also referred to hereafter as "the proposed rule") (81 FR 43155). The proposed rule would require that certain data elements, most of which may be submitted by importers in ACS, be submitted in the Automated Commercial Environment (ACE), which is set to replace ACS, in order to facilitate FDA's initial admissibility review of FDA-regulated products being imported or offered for import into the U.S.

Note: On June 27, 2016, OMB approved FDA's request to revise the ICR approved under OMB Control Number 0910-0046 pursuant to FDA's final rule that deemed products meeting the statutory definition of "tobacco product" to be subject to the FD&C Act. The present ICR revision request could not account for that June 27, 2016, approval by OMB because by that time FDA's Notice of Proposed Rulemaking for the proposed rule was in the very final stages of clearance. The 0910-0046 ICR revision request approved by OMB on June 27, 2016, may affect the ultimate total burden for the ICR approved under OMB 0910-0046, but should not affect the estimated additional annualized burden that would result from finalization of the proposed rule.

Although primary responsibility for administering U.S. laws relating to imports is exercised by U.S. Customs and Border Protection (CBP), FDA is responsible for determining whether or not imported articles regulated by FDA 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 proposed rule and this corresponding revision of

this ICR would improve FDA's ability to effectively and efficiently conduct its initial admissibility review of the growing number FDA-regulated import lines.

There are several important historical legislative and executive milestones leading up to the expected implementation 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 planned successor to ACS. ACS and ACE are electronic systems 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 as part of a single portal system through which industry will transmit 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 must participate in ITDS in order to require documentation 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" to the ITDS single portal system.

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 an importer of record must file with CBP. An import entry line (or "line") is each portion of an entry that is listed as a separate item on an entry document. CBP requires importers to submit entry line information, such as the entry number, importer of record, country of origin, etc., in ACS or in ACE for generally all merchandise imported into the U.S. unless specifically exempt.

Currently, if the entry contains lines of products regulated by FDA, CBP collects additional information about FDA-regulated products in ACS, specifically: (1) the complete FDA Product Code; (2) FDA Country of Production; (3) FDA manufacturer and shipper; (4) and the ultimate consignee. At that time filers also have the option of submitting in ACS any applicable FDA Affirmations of Compliance, which relate to certain requirements specific to certain types of FDA-regulated products and may assist FDA in expediting the initial admissibility screening and further review of the entry.

After the importer submits this data in ACS, CBP electronically transfers the data to FDA. Currently over 96% of all entries filed with CBP are filed electronically (through the Automated Broker Interface (ABI)), and that percentage is expected to increase after implementation of

ACE. Because CBP relays the data to FDA electronically, generally the importer of record 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 line information to determine potential risks associated with each 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 would 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 submitted by the importer of record and may request additional information to make an admissibility determination and/or may examine or sample the FDA-regulated product.

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 U.S. 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 currently approved for collection by OMB under OMB Control Number 0910-0046. 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.

2. Purpose and Use of the Information Collection

This collection of information would collect certain information from importers of record importing or offering FDA-regulated products for import into the United States. Importers would be required to submit this information in ACE pursuant to FDA's proposed 21 CFR Part 1 Subpart D, each time the importer imports or offers for import an FDA-regulated product into the U.S. As noted above, this requested revision to this approved collection of information will allow FDA to gather important and useful information about FDA-regulated products being imported or offered for import into the United States, beyond what information is currently being submitted in ACS. The collected information is used by FDA to initially electronically screen and review FDA-regulated products being imported or offered for import into the U.S. and 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. As ACE is implemented, automated "May Proceed" determinations by FDA should increase, and the international trade community will be able to more easily and efficiently import FDA-regulated products that pose a low public health risk into the U.S.

FDA estimates that at least 96% of respondents will use electronic means to 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 products and quantities are arriving at which ports, from which manufacturers, and from what countries, etc. We expect the collection of information required by the proposed rule and the improved information technology capabilities of ACE and ITDS 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 that would be required by 21 CFR Part 1 Subpart D, for which FDA is requesting OMB approval, does not duplicate what is required by CBP.

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 proposed 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 FDA's proposed regulation 21 CFR Part 1 Subpart D should not impose any undue burden on small businesses or other small entities.

As discussed the Preliminary Regulatory Impact Analysis (PRIA) for the proposed rule (available online here) FDA estimates that 57,513 out of the 59,292 owners or consignees of imported products are small businesses and that 3,970 out of the 4,010 entry filers are small businesses. As also discussed in the PRIA, the proposed rule would affect small businesses and larger businesses in a similar manner. The total annual burden per respondent should generally scale linearly with the annual number of entry lines that include FDA-regulated products that a respondent is responsible for, and that number should generally scale linearly in accordance with the size of the respondent business.

Furthermore, if needed, any filer can obtain assistance from their local FDA district, or from an FDA ACE "help desk" which FDA has maintained since the implementation of the ACE pilot program.

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 as or before goods arrive in port to enable FDA to determine if the product will be allowed into port immediately, or 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 import. Therefore, it is essential for FDA to receive information regarding FDA-regulated products 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 with regards to which products FDA should admit without further review, which products to detain without physical examination, and which products to allocate further resources to, for example, by physically examining and/or sampling and testing a product.

If the information were to be submitted on a less frequent basis, FDA could not adequately meet its statutory responsibilities to regulate imported products, nor could it control potentially dangerous products from entering the U.S. marketplace. In turn, information submitted less frequently could have an adverse effect on the American population, who is the final purchaser and consumer of these products.

This requested revision of this information collection request is vital for FDA to continue to keep the U.S. safe from violative FDA-regulated products in a rapidly expanding, complex, and demanding international trade environment. If FDA were not able to collect FDA-specific data elements in ACE, FDA's ability to determine the risk level of imported FDA-regulated products would be severely hampered. The required data elements in the proposed rule are the key data/information that would most assist the Agency in making initial admissibility determinations, and are also those data elements that FDA currently most often requests from importers during a manual review of an entry filed in ACS where the importer opted not to submit the information at the time of filing entry. By requiring certain data elements when they are applicable, 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 to FDA each time the respondent imports an FDA-regulated product to the U.S.

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 to the extent required by law.

FDA conducts filer evaluations to make certain 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 has provided an opportunity for public comment on the information collection requirements of the proposed rule, as published in the FEDERAL REGISTER of July 1, 2016 (81 FR 43155).

In developing the proposed rule and this associated collection of information, HHS/FDA has also consulted with appropriate agencies such as CBP, DHS and the Department of the Treasury, and responded to their comments on the NPRM, including their comments on the PRA section.

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

Note: For reasons noted in section A(1) above, the present 0910-0046 ICR revision request could not account for OMB's recent June 27, 2016, approval of the 0910-0046 ICR. However, although the 0910-0046 ICR revision request for approved by OMB on June 27, 2016, may affect the final total burden for the ICR approved under OMB 0910-0046, it should not affect the estimated additional annualized burden that would result from finalization of the proposed rule.

FDA is proposing to revise the information collection request (ICR) currently approved under OMB Control Number 0910-0046 to adjust it for increases in the number of import lines containing FDA-regulated products and to account for the provisions of FDA's proposed 21 CFR Part 1 Subpart D that provide for collection of information from importers via ACE. We have estimated that under the proposed rule more information will be collected in ACE than has been collected in ACS, primarily because the proposed rule would require submission of certain data elements in ACE that are currently 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 from the importer of record. In 2015 the average time for OASIS to process an ACS import entry of an FDA-regulated product and issue an automated "May Proceed" was approximately 24 minutes, whereas the average time for an FDA-reviewer to manually review the entry and issue a "May Proceed" determination was about 28 hours. Further, we (FDA) expect the average time for FDA to issue an automated "May Proceed" to be faster in ACE.

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 additional entry information required by CBP (such as the entry number, importer of record, 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 collection of certain information about import lines that are or contain radiation emitting electronic products, pursuant to proposed 21 CFR Part 1 Subpart D § 1.77, is

covered by the "Reporting and Recordkeeping for Electronic Products - General Requirements," information collection approved by OMB under Control Number 0910-0025.

- 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 respondents to this collection of information are domestic and foreign "importers of record" of FDA-regulated articles being imported 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 FDA estimates there are about 59,292 owners or purchasers who seek to import FDA-regulated articles into the United States on an annual basis, and FDA has 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% will file their import entries themselves. FDA thereby estimates 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 x (100-97.7) percent).

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 (as either required or optional submissions, depending on the data element) and already approved for collection under OMB Control Number 0910-0046. Two of these four new data elements would be required by proposed 21 CFR 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 would help to facilitate electronic notice under § 1.94 for certain FDA actions. The other two new data elements would be required

by proposed 21 CFR 1.79, which applies only to tobacco products, and are the name and address of the ACE filer and the 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 21 CFR 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 optional affirmations of compliance information currently collected in ACS for all lines in an entry is estimated at 8.4 minutes (0.14 hours). FDA 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 per entry 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%) 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 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.

To correspond with the PRIA methodology, we are converting the average of 7.4 minutes per entry into the average time per line. In 2014, when OMB most recently approved this ICR, there was an average of approximately 4.166 lines per entry for FDA-regulated products. We therefore estimate that it takes a filer approximately 1.776 minutes per line, which is approximately 0.0296 hours (= 7.4 minutes divided by 4.166 lines), 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.

We are adjusting the current estimated burden for this information collection approved under OMB Control Number 0910-0046 to account for 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 (for an annualized average of 35,133,681 lines in years one, two, and three). Pursuant to the PRIA, we are also adjusting the number of filers from 3,736 to 4,010. The adjusted hourly burden, without yet accounting for the additional burden of the proposed rule, is approximately 1,039,957 hours per year, calculated as follows:

Table 1 – Currently Approved Burden					
Activity	Number of Respondents	Number of Responses per	Total Annual Responses	Average Burden per Response	Total hours

		Respondent (approximate)		(approximate)	
Reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing, reviewing, and filing each entry	4,010	8,761	35,133,681	0.0296 hours (1.776 minutes)	1,039,957

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

Using the estimates in the PRIA for the proposed rule, we have estimated that the proposed rule would impact 33,988,154 import lines in the first year. The proposed rule would not require additional collection of information for import lines of radiation emitting electronic products or foods other than acidified foods, low acid canned foods, and food contact substances.

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 of the PRIA (Option 1) for the proposed rule that affect our estimate of the additional annual reporting burden are:

- Respondents (filers) would have to become aware of the rule requirements, which would 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 (owners or purchasers) 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 21 CFR 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 (filers) would require an administrative worker to complete an entry request for each import line and quality check using software that is connected to ACE, and that

this would require about 2 minutes (approximately 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 21 CFR 1.72(b)(ii)) is not subject to the requirements of the PRA, we have reduced this estimated time to 1.8 minutes (approximately 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 entry request for each import line and quality check using software that is connected to ACE because the respondent would have to adjust to the new system and data elements.

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 not collected in ACS, and the proposed rule requiring submission of some data elements in ACE that are currently collected as optional Affirmations of Compliance in ACS.

We expect that some filers who were not submitting the optional data elements in ACS would have to change their submissions to comply with the proposed rule, if finalized. Notably, however, the submission rates of some Affirmations of Compliance in ACS are quite high, although they vary depending on the commodity. 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, we estimate that medical device lines would make up about half of all import lines that would be impacted by the proposed rule. On the other hand, for example, only 24% of animal drug import lines had at least one of the Affirmations of Compliance code, although, based on 2014 and 2015 data, we estimate that animal drugs would make up less than .5% of all import lines that would be affected by the proposed rule.

As noted above, 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 three years.

In accordance with the above discussion, 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

Activity	Number of Respondents	Number 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

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

Activity	Number of Respondents	Number 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 (0.225minutes)	127,456
Total Hours….	……	……	……..	……...	129,461

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 (1,117,238 recurring hours + 129,461 one-time hours) and 1,117,238 hours recurring after the first year.

As noted above, the current adjusted estimated burden for this information collection, not yet accounting for the estimated additional burden of the proposed rule, is 1,039,957 hours. We have estimated that the total burden under this ICR, revised to include the estimated additional annual reporting burden under the proposed rule in addition to the adjusted current annual reporting burden, would be 2,286,656 hours in the first year (=1,039,957 current burden hours + 1,117,238 recurring hours + 129,461 one-time hours) and 2,157,195 hours annually after the first year (= 1,039,957 current burden hours + 1,117,238 recurring hours).

12b. Annualized Cost Burden Estimate

As discussed in section 12a above, we are adjusting the current estimated burden for this information collection approved under OMB Control Number 0910-0046 to 1,039,957. The currently 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. The hourly wage of a GS-10 step 5 employee in 2015, excluding other compensation such as benefits like health insurance and retirement contributions, was $52,915 per year, or approximately $25.44 per hour. In accordance with the methodology used by the PRIA for the proposed rule, we are increasing this salary / hourly wage amount by 100 percent to include other compensation such as benefits like health insurance and retirement contributions, i.e., “overhead costs and benefits,” for a total salary of $105,830 per year, which is $58.88 per hour. Accordingly, we are updating the annualized cost burden estimate of this ICR –without yet accounting for the additional burden of the proposed rule– to $67,406,531.

Adjusted Currently Approved Estimated Burden, Not Accounting for the Proposed Rule

Type of Respondent	Total Burden hours	Hourly Wage Rate	Total Respondent Costs
Filer	1,039,957	$58.88	$61,232,668

The costs of the additional information collection pursuant to the proposed rule, if finalized, are directly related to the time it would 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 would be recurring (preparing the required information for unique lines, and quality checking data and submitting the data into ACE) and other activities would occur one time (review and familiarization with the rule, and the 12.5 percent more time required for quality checks and submission into ACE in the first year). As also noted above in section 12a, we have estimated that the number of impacted import lines will grow at an average rate of about 3.3 percent per year, and we have annualized those increases over years one, two, and three.

In accordance with the PRIA for the proposed rule:

- The reoccurring activity of preparing the required information for unique lines would be performed by an administrative worker at a total average hourly wage rate of $34.16, which includes include overhead costs and benefits.
- The reoccurring activity of quality checks and data submission into ACE would 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 would be performed by operations managers at an average hourly wage rate of $112.70, which includes overhead costs and benefits.
- The 12.5 percent more 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, we estimate the additional annualized cost burden estimate under this ICR pursuant to the proposed rule (not yet accounting for the adjusted currently approved burden) would be $89,117,319 in the first year ($79,532,261 recurring cost + $9,585,058 one-time cost) and $79,532,261 annually recurring thereafter:

Estimated Annual Recurring Cost Burden Pursuant to the Proposed Rule

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Preparing the required information (applies to unique lines only)	63,828	$34.16	$2,180,364
Quality checks and data submission into ACE	1,053,410	$73.43	$77,351,896
Total			$79,532,261

Estimated One-Time Cost Burden Pursuant to the Proposed Rule

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs

Review and familiarization with the rule	2,005	$112.70	$225,963.50
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	127,456	$73.43	$9,359,094
Total			$9,585,058

When the adjusted current annualized cost burden estimate ($61,232,668) and the additional annualized cost burden estimate pursuant to the proposed rule are aggregated, the total revised annualized cost burden estimate under this ICR would be $150,349,987 in the first year ($61,232,668 current cost + $79,532,261 additional recurring costs + $9,585,058 additional one-time cost) and $140,764,929 annually thereafter ($61,232,668 current cost + $79,532,261 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 would fall under the cost of CBP's ACE, we do not account for those costs in this ICR.

14. Annualized Cost to the Federal Government

The currently 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 currently 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. Therefore, the currently approved version of this ICR estimates that the annualized cost to the federal government is $10,281,925 per year (=$66,335 * 155 FTEs).

We do not expect the number of FTEs required to review importers entry notices to change under the proposed rule. However, in accordance with the methodology used by the PRIA for the proposed rule, we are adjusting our estimate of the salary of an FDA import entry reviewer to the hourly wage of GS-10 step 5 employee in 2015 (which, when excluding overhead costs and benefits, is $52,915 per year) and increasing this salary amount by 100 percent to include overhead costs and benefits, to $105,830 per year.

Accordingly, we are adjusting our estimate of the annualized cost to the federal government to $16,403,650 per year (=$105,830 * 155 FTEs).

15. Explanation for Program Changes or Adjustments

As discussed in greater detail above, we are requesting OMB's approval to revise this ICR to account for additional collection of information provisions in FDA's proposed 21 CFR Part 1 Subpart D to account for several adjustments and program changes:

- We are adjusting the estimated burden currently approved under OMB 0910-0046 (not yet accounting for the proposed rule) from 522,421 hours to 1,039,957 hours, which is an adjustment increase of 517,536 hours, to account for an increase in FDA-regulated import

lines and to correct for a previous accidental oversight on our part, as we had by accident lapsed in adjusting for increases in the number of FDA-regulated entries for several iterations of this ICR.

- As explained in detail above, we are requesting a program change increase of 1,246,699 hours in the first year and 1,117,238 hours recurring after the first year to account for additional collection of information provisions in FDA's proposed 21 CFR Part 1 Subpart D.

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

We are 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.