

## Importer's Entry Notice

OMB No. 0910-0046

### SUPPORTING STATEMENT

**Terms of Clearance:** None.

#### A. Justification

1. Circumstances Making the Collection of Information Necessary

Section 801 of the FD&C Act charges the Secretary of Health and Human Services (HHS), through the FDA, with the responsibility of assuring foreign origin FDA regulated foods, drugs, cosmetics, medical devices, radiological health, and tobacco products offered for import into the United States meet the same requirements of the act as do domestic products, and for preventing products from entering the country if they are not in compliance. The discharge of this responsibility involves close coordination and cooperation between FDA headquarters and field inspectional personnel and the U.S. Customs Service (USCS), as the USCS is responsible for enforcing the revenue laws covering the very same products.

This collection of information is being used by FDA to review and prevent imported products from entering the United States if the products do not meet the same requirements of the FD&C Act as domestic products.

Until October 1995, importers were required to file manual entry(ies) on OMB-approved forms which were accompanied by related documents. Information provided by these forms included information such as country of origin, name of the importing vessel, entry number (assigned by USCS), port of entry, the port of lading and unloading, value in U. S. dollars, shipper or manufacturer, importer of record, original consignee, broker, broker's reference number and USCS house box number, bill of lading number, location of goods, etc. FDA did away with use of the paper forms effective October 1, 1995 to eliminate duplicity of information and to reduce the paperwork burden both on the import community and FDA. FDA then developed and implemented an automated nationwide entry processing system, which enabled FDA to more efficiently obtain and process the information it requires to fulfill its regulatory responsibility.

Most of the information FDA requires to carry out its regulatory responsibilities under section 801 is already provided electronically by filers to USCS. Because USCS relays this data to FDA using an electronic interface, the majority of data submitted by the entry filer need be completed only once.

In addition to the information collected by USCS, FDA requires four additional pieces of information that were not available from USCS's system in order to make an admissibility decision for each entry. These data elements include the FDA Product

Code, FDA country of production, manufacturer/shipper, and ultimate consignee. OMB has previously approved the automated collection of these four data elements for tobacco products that filers could provide to FDA along with other entry-related information. Providing this information to FDA results in importers receiving an FDA admissibility decision more expeditiously, e.g., the quantity, value, and Affirmation(s) of Compliance with Qualifier(s).

2. Purpose and Use of the Information Collection

The respondents to this collection of information are importers of FDA-regulated products who are private businesses importing goods from foreign countries.

In turn, if the information was not submitted, it would have an adverse effect on the American consumer because of a reduction in speed experienced when filing, as speedy clearance saves filers demurrage and other significant costs incurred when shipments are delayed for regulatory review.

3. Use of Improved Information Technology and Burden Reduction

FDA's electronic screen criteria program and its interface with the Automated Commercial System was created to reduce burden for respondents who formerly responded to this collection through a paper-only basis. One data element required by FDA (the FDA product code) necessitated FDA to provide filers a diskette containing the "FDA Product Code Builder" software/files and authorized them to make copies as necessary. FDA designed the software so the Product Code Builder filers can be updated electronically. Filers (and FDA personnel) simply download new/revised/deleted data. The automated Product Code Builder program has replaced the hardcopy manual which eliminated the need for update and distribution of as many as 10,000 copies and updates to be developed and distributed. This represents another very significant reduction in paper and resources for both the private and public sector.

Another important benefit of the automation of the previous manual paper-based system has been the intelligence gained (and used) as the database has expanded. The automated system has been an excellent tool in assisting FDA to more effectively and efficiently manage and conduct its import operations and to better meet its regulatory responsibility.

The automated system has also been of great value to the FDA personnel responsible for planning and delegating import work, e.g., what products and quantities are arriving at which ports, from which manufacturers, and from what countries, etc. FDA previously relied on information obtained from Census and USCS records which often was several years old.

FDA estimates that 100% of the respondents will use the electronic submission system associated with this collection to fulfill the agency's requirement for import entry notices.

4. Efforts to Identify Duplication and Use of Similar Information

The information for which FDA requests OMB approval is unique to the FDA and is not duplicated by any other government agency.

5. Impact on Small Businesses or Other Small Entities

The information provided by filers is voluntary and does not impose any undue burden on small businesses. If needed, filers can obtain assistance from their local FDA district. Since the implementation of the automated system, FDA has maintained "help desks" to resolve filer questions/problems.

6. Consequences of Collecting the Information Less Frequently

Respondents to this data collection are expected to respond occasionally, or when imported shipments arrive in the United States. Information must be submitted as goods arrive in port to enable FDA to determine if the product will be allowed into port immediately, or held pending further FDA review.

If the information is submitted on a less frequent basis, or is eliminated, FDA could not adequately meet its statutory responsibilities to regulate imported products, nor control potentially dangerous products from entering the U.S. marketplace. In turn, information submitted less frequently would have an adverse effect on the American population, who is the final purchaser and consumer of these products. Additionally, to revert back to a manual process would greatly reduce the speed filers now receive and to which they have become accustomed. This would be very disadvantageous to importers, as speedy clearance saves them demurrage and other significant costs incurred when shipments are delayed for regulatory review.

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

Information for this data collection is reported to FDA each time a shipment is imported into the United States by the respondent to allow FDA to either accept each line of the shipment, or indicate that product requires further FDA review.

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

FDA conducts filer evaluations to make certain accurate information is being transmitted by filers. This is accomplished by comparing filers' paper records to data FDA received electronically.

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

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of 11/27/2013 (78 FR 70951). No comments were received.

FDA field personnel maintain frequent contact with their local filer firms, either by phone or by meetings, to keep the import community up-to-date with regard to import policy and procedures. FDA also conducts one-on-one meetings with individual filer firms to provide instruction on transmitting entry data accurately and successfully. In addition, FDA field personnel are in frequent contact with their local USCS client representatives

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 considered in review guidelines in 21 CFR 20.61.

11. Justification for Sensitive Questions

There were no questions asked of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

The basis for computing the annual reporting burden is derived from the basic processes and procedures used in fiscal years (FY) 1995 through 2013 and has remained the same with the exception that the number of entries has increased. The total number of entries, less the disclaimer entries, represents the total FDA products entered into the automated system. Historically, 53 percent of all entries entered into the automated system have been entries dealing with FDA-regulated products. The number of respondents is a count of filers who submit entry data for foreign-origin FDA-regulated products. The estimated reporting burden is based on information obtained through contact by FDA with 9 or less potential respondents.

12 a. Annualized Hour Burden Estimate

The annual estimated burden imposed by this collection of information is 522,421 burden hours (For Non-Tobacco 3,406 estimated annual respondents times 1,089 expected responses equals 3,709,134 total annual responses).

(For Tobacco, (330 estimated annual respondents, times 68 expected responses equals 22,440). The total annual response (for both Non-Tobacco and Tobacco) is 3,731,574 multiplied by the expected hours per response [0.14 hours] equals an estimated 522,421 total hours.)

The hourly burden for this information collection is based on FDA's averaging of data obtained during a survey of nine representative filers nationwide and FDA's experience. For purposes of comparison of hourly burden, the filers also were requested to provide the same information with regard to filing entries manually. FDA felt that the average time for completing either electronic or manual entries was very similar.

Based on data collected by FDA's survey of nine filers and its experience, the total annual burden to the import community to submit information electronically for 3,731,574 average annual responses was 522,421 hours. The previously OMB-approved hours per response (0.14 hours) are expected to remain the same.

This burden includes the time FDA estimates it will take respondents to compile and provide documents to FDA for those entries where FDA cannot make an admissibility decision based on the electronic data alone. Based on the survey of nine filers and FDA's past experience, FDA estimates that there will be no additional costs to provide import data electronically to FDA, as filers already have equipment and software in place to

enable them to provide data to USCS via the automated system. Therefore, no additional software or hardware need be developed or purchased to enable filers to file the FDA data elements at the same time they file entries electronically with USCS.

The information collection for the Prior Notice and Regulation Rules is separate from the burden reported, herein, and is approved under OMB control number 0910-0520.

The annual recordkeeping requirements for this collection are covered by the United States Customs Service information collection “Customs Modernization Act Recordkeeping Requirements” (OMB No. 1651-0076, which expires 11/30/2015).

FDA estimates the burden of this information collection is as follows:

Table 1.--Estimated Annual Reporting Burden					
FDA Imported Products	No. Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden Per Response	Total Hours
Non-Tobacco	3,406	1,089	3,709,134	.14 (8 minutes)	519,279
Tobacco	330	68	22,440	.14 (8 minutes)	3,142
Total					522,421

12b. Annualized Cost Burden Estimate

The total estimated cost burden for this collection of information is based upon performing a similar position in the government as private industry. The cost to respondents is estimated to approach the hourly cost of a GS-10, step 5 worker, or \$31 per hour. Therefore, the cost associated with this collection is \$ 16,195,051.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Industry Analyst	522,421	\$31.00	\$16,195,051

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.

14. Annualized Cost to the Federal Government

Salary of the FDA entry reviewer varies; however, the average salary is estimated to be GS-10 at an annual base of \$66,335. It is estimated that 155 Full Time Equivalents (FTEs) are required to review the importers entry notice. Therefore, the cost for salaries is \$10,281,925 per year.

15. Explanation for Program Changes or Adjustments

The burden for this collection of information is expected to increase by 1,242 reporting hours due to an expected increase in the number of Tobacco respondents. This adjustment is a result of a revised estimate in the number of tobacco product importers expected to report to the FDA on the listing of regulated products for this information collection.

The previously approved OMB burden estimate for Tobacco products was 1,900 hours. The current overall increase of 1,242 hours to 3,142 total burden hours is attributed to an expected increase in the number of respondents by 130 (from 200 to 300 respondents) and corresponding increase in the number of annual responses by 8,840 (from 13,600 responses to 22,400 responses). The total burden increase, therefore, is expected to increase by 1,242 hours (130 additional respondents x 68 annual responses equals 8,840 additional responses. 8,840 additional responses times 0.14 hours equals an approximate 1,242 burden hour increase, due to rounding.)

FDA Imported Products	No. Respondents	Annual Frequency Per Response	Total Annual Response	Hours Per Response	Total Hours
Tobacco (New)	330	68	22,440	.14 (8 Minutes)	3,142
Tobacco (Old)	200	68	13,600	.14 (8 Minutes)	1,900
Increase	130		8,840		1,242

This increase is due to an expected increase in the number of tobacco product importers. This expected increase was calculated using actual importer reports submitted to FDA and FDA's expertise.. The revision to this collection of information expands the universe of respondents being regulated under the FD&C Act, as amended, to add additional expected importers of tobacco products.

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

The Agency is not seeking to display the expiration date for OMB approval of the information collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.