Importer's Entry Notice

0910-0046
SUPPORTING STATEMENT

REVISION

A. Justification

1. Circumstances Making the Collection of Information Necessary

Abstract

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) (Public Law 111-31) into law. The Tobacco Control Act amended the Federal, Food, Drug, and Cosmetic Act (FD&C Act) by adding a new chapter granting the Food and Drug Administration (FDA) important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

With the passage of the Tobacco Control Act, section 801 of the FD&C Act was amended to add tobacco products to the inventory of FDA-regulated products. The new section 801 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. This collection of information was most recently approved by the Office of Management and Budget (OMB) on August 10, 2009 and received an expiration date of August 31, 2012 (ICR Reference Number 200905-0910-006.) However, because tobacco products had only been added to the FDA's list of regulated products in June 2009, this collection of information did not reflect the collection of information for tobacco products offered for import into the United States and for preventing these products from entering the United States if they did not meet the same requirements of the act as domestic products. The revision to this collection of information expands the universe of respondents being regulated under the FD&C Act, as amended, to include importers of tobacco products, and corrects the collection's burden to account for the addition of tobacco products to the list of FDA-regulated 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 unlading, 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 done only once.

During the most recent OMB approval of this information collection package in August 2009, FDA noted that in order to make an admissibility decision for each entry, FDA required four additional pieces of information that were not available from USCS's system. These data elements were the FDA Product Code, FDA country of production, manufacturer/shipper, and ultimate consignee. In the revision of this information collection package, OMB approval for the "automated" collection of these four data elements for tobacco products is being requested. Under the most recent approval, FDA noted that there were additional data elements filers could provide to FDA along with other entry-related information. Providing this information to FDA could result in importers receiving an FDA admissibility decision more expeditiously, e.g., the quantity, value, and Affirmation(s) of Compliance with Qualifier(s).

This information collection does not relate to the American Recovery and Reinvestment Act of 2009 (ARRA).

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.

This collection of information gathers data about FDA-regulated products being imported into the United States. The revision to this collection of information reflects an increased number of respondents and burden being recognized by the agency as a result of the addition of tobacco products to the list of FDA-regulated products under the Tobacco Control Act.

At each U.S. port of entry (seaport, landport, and airport) where foreign-origin, FDA-regulated products are offered for import, FDA is notified through Custom's Automated Commercial System (ACS) by the importer (or his agent) of the arrival of each entry. Following such notification FDA reviews relevant data to ensure the imported product

meets the standards as required for domestic products, decides on the admissibility of the imported product , and informs the importer and USCS of its decision. A single entry frequently contains multiple lines of different products. FDA may authorize products listed on specific lines to enter the U.S. unimpeded, while other products listed in the same entry may be held pending further FDA review/action.

All entry data pass through a screening criteria program resident on a USCS computer. This screening program was developed and is maintained by FDA. This electronic screening criteria module makes the initial screening decision on every entry of foreign-origin FDA-regulated product. Almost instantaneously after the entry is filed, the filer receives FDA's admissibility decision for each entry, i.e., “MAY PROCEED” or “FDA REVIEW.”

Examples of FDA's need to further review an entry may result from some products originating from a specific country or manufacturer known to have a history of problems, FDA having no previous knowledge of the foreign manufacturer and/or product, or an import alert may have been issued, etc. The system assists FDA entry reviewers by notifying them of information, such as the issuance of import alerts, thus averting the chance that such information will be missed in their review.

Since the inception of the interface with ACS, FDA's electronic screening criteria program is applied nationwide. This eliminates issues such as "port shopping," (attempts to intentionally slip products through one FDA port when refused by another, or filing entries at a port known to receive a high volume of entries.) Every electronically submitted entry line of foreign-origin FDA-regulated product undergoes automated screening and the screening criteria can be set to be as specific or as broad as applicable; changes are immediately effective. This capability is of tremendous value in protecting the public if there is a need to immediately halt specific product from entering the United States.

The program may also explain the consequences that can occur if the data is not collected. If the collection of information 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, if the information was no submitted, it would have an adverse effect on the American consumer because of a reduction in speed filers now experience when filing, as speedy clearance saves them 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 ACS was created to reduce burden for respondents who used to respond 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.

The collection of information increases the number of respondents to reflect FDA's regulation of tobacco products. An additional 200 respondents are estimated to be included in this collection of information, and all are expected to be businesses such as tobacco manufacturers and importers.

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. The new respondents added to this data collection will respond occasionally, as responses are required each time a shipment of FDA-regulated goods (e.g., tobacco products) is due in port. (It is anticipated that each respondent will respond an average of 68 times per year.) 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 (including imported tobacco 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, for whom 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

   Opportunity for public comment on the information collection requirements was published in the Federal Register on November 4, 2010 (75 FR 67981). No comments were received.

   FDA continues to communicate routinely with the National Customs Brokers and Forwarders Association of America (NCBFAA), the major trade association of firms who file import entries and provide required data to FDA. Members have and continue to express their approval of FDA's automated entry process. The principal contact for the NCBFAA can be reached at (415) 904-8334, who as Chairman of the Regulatory Agency Committee represents the interest of all members/brokers in FDA matters.

   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

OMB approved this collection on August 10, 2009 and published its notice of approval in the Federal Register on September 1, 2009 (74 FR 45221). The collection was approved for a period of three years and was granted an expiration date of August 31, 2012.

The basis for computing the annual reporting burden is derived from the basic processes and procedures used in fiscal year (FY) 1995 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 OMB-approved burden for this collection of information is 519,279 burden hours (3,406 estimated annual respondents times 1,089 expected responses equals 3,709,134 total annual responses. The total annual responses multiplied by the expected hours per response [0.14 hours] equals an estimated 519,279 hours.) The total burden for this collection of information was calculated for all FDA-regulated products prior to June 22, 2009, and did not include burden estimates for tobacco products. This supporting statement's burden reflects the addition of tobacco products to the list of FDA's regulated products and increase in the respondent universe resulting from the passage of the Family Smoking Prevention and Tobacco Control Act of 2009.

The original (non-tobacco) hour burden for this information collection was based on FDA's averaging data obtained during FDA's survey of nine representative filers nationwide. For purposes of comparison of hour 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 the same.

Based on the original data collected by FDA's survey of nine filers, the total annual burden to the import community to submit information electronically for 3,709,134 average annual responses was 519, 279 hours. In this revision, FDA estimates that 200 additional entry filers will submit approximately 13,600 entries of imported tobacco products to FDA per year (200 entry filers x 68 expected responses for each filer per year). The hours per response (0.14 hours) are expected to remain the same for tobacco importers, and the total annual burden for FDA regulated tobacco products is expected to be 1,900 hours (13,600 annual entries x 0.14 hours).

The addition of tobacco products to FDA's list of regulated products is therefore expected to increase the total burden hours for this collection of information by 1,900 hours to 521,179 hours (519,279 + 1,900 hours), and this burden amount includes the

time FDA estimates it will take filers 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 08/31/2012).

FDA estimates the revised reporting burden (including burden for tobacco product filers) for this collection of information is as follows:

Estimated Annual Reporting Burden[1]					
FDA Imported Products	No. Respondents	Annual Frequency Per Response	Total Annual Responses	Hours Per Response	Total Hours
Non-Tobacco (expires 08/31/12)	3,406	1,089	3,709,134	.14 hr	519,279
Tobacco (new burden)	200	68	13,600	.14 hr	1,900
Total	3,606		3,722,734	.14 hr	521,179

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 $1,615,655 (521,179 hours multiplied by $31 per hour).

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 $65,387. It is estimated that 154.7 Full Time Equivalents (FTEs) are required to review the importers entry notice. Therefore, the cost for salaries is $10,115,368 per year ($65,387 annual salary multiplied by 154.7 FTEs).

15. Explanation for Program Changes or Adjustments

The revision to this collection of information is expected to increase burden by 200 respondents and 1,900 hours due to a program change incurred by the revision to section 801 of the Federal, Food, Drug, and Cosmetic Act (FD&C Act) resulting from the passage of the Family Smoking Prevention and Tobacco Control Act of 2009 (Tobacco Control Act). This program change resulted in an increase in the importer respondent universe due to the addition of tobacco products to the list of FDA-regulated products under the FD&C Act.

Because the addition of 1,900 hours represented only 4/10ths of one percent (0.0037) of the entire burden total, FDA initially felt that the additional burden being requested by this collection (200 respondents and 1,900 hours) was contained in the burden already represented by this collection (521,279 hours). However, the adding of respondents and hours without a corresponding revision of this collection of information could make this a bootleg collection under the Paperwork Reduction Act, and FDA is revising this collection to reflect the impact of the passage of the Tobacco Control Act and correct the omission of tobacco product import burden from this collection.

In 2010, FDA reviewed existing OMB-approved information collections for any impact the passage of the Tobacco Control Act might have and discovered that this collection might be a candidate for revision. With the passage of the Tobacco Control Act, section 801 of the FD&C Act was amended to add tobacco products to FDA-regulated products. Section 801 charged the Secretary of Health and Human Services (HHS), through the FDA, with assuring foreign origin FDA regulated products, including tobacco products, offered for import into the United States meet the same requirements of the act as do domestic products and with preventing products from entering the country if they are not in compliance. Most of the information FDA requires to carry out its regulatory responsibilities under section 801 is already provided electronically by filers to the United States Customs Service (USCS). USCS relays this data to FDA using an electronic interface, so the majority of data submitted by the entry filer need be done only once. As noted in Item 1 of this supporting statement, the Secretary's responsibility involves close coordination and cooperation between FDA inspectional personnel and the U.S. Customs Service (USCS), since the USCS is responsible for enforcing the revenue laws covering the very same products.

The burden is being revised to add 1,900 hours annually to the existing burden (200 importers of tobacco products x 68 responses/respondent = 13,600 annual responses x

0.14 hours per response). The total annual burden for both tobacco and non-tobacco FDA-regulated products is now estimated at 521,179 burden hours (519,279 approved burden hours plus 1,900 new burden hours attributed to the classification of tobacco as an FDA-regulated product.)

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

No tabulation of the data is planned or anticipated.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement identified in Item 19, "Certification for Paperwork Reduction Act Submission," of OMB Form 83-I.