

## SUPPORTING STATEMENT FOR

Importer' s Entry Notice

OMB No.0910-0046

Docket No. 2005N-0290

Expires 05/31/2009

### Section A -Justification

#### 1. Circumstances Necessitating Information Collection

Section 801 of the Food, Drug, and Cosmetic Act (the act) (Attachment A) charges the Secretary of Health and Human Services (HHS), through the Food and Drug Administration (FDA), with the responsibility of assuring foreign origin FDA regulated foods, drugs, cosmetics, medical devices, and radiological health products offered for import into the United States meet the same requirements of the FD&C 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.

Up until October 1995, entry information of interest to FDA was required to be provided by importers filing manual entry(ies) an OMB-approved FDA Form 700 set, Importer's Entry Notice, which included FDA Forms 701,702, and 703, and which were accompanied by related documents, e.g., invoices, Custom's Forms 3461 or 3461/Alt, certificates of affirmation of compliance, etc. Information provided by the 700 set included 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 Custom's house box number, bill of lading number, location of goods, etc.

FDA made a decision to eliminate use of the FDA 700 set, effective no later than FY 1996 (October 1, 1995), for several reasons, e.g., to reduce the paperwork burden both on the import community and FDA, to eliminate duplicity of information, and, most important, FDA developed and implemented nationwide an automated entry processing system, which enables 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 is already, provided electronically by filers to Customs. Because Customs relays this data to FDA using an electronic interface, the majority of data submitted by the entry filer need be done only once.

In order to make an admissibility decision for each entry, FDA needs four additional pieces of information that are not available from Custom's system. These data elements are the FDA Product Code, FDA country of production, manufacturer/shipper, and ultimate consignee. It is the "automated" collection of these four data elements for which OMB approval is requested. FDA construes this request as an extension of the prior approval of collection of this data via a different media, i.e., paper. There are additional data elements which filers can provide to FDA along with other entry-related information which, by doing so, may result in their receiving an FDA admissibility decision more expeditiously, e.g., the quantity, value, and Affirmation(s) of Compliance with Indicator(s).

#### 2. How, by whom, -Purpose of Collection

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 are required for domestic products, makes an admissibility decision, and informs the importer and USCS of its decision. A single entry frequently contains multiple lines of different products. FDA may authorize specific lines to enter the U.S. unimpeded, while others in the same entry are to be held pending further FDA review/action.

An important feature programmed into the automated system all entry data to pass through a screening criteria program resident on Custom's computer. Even though this screening module resides on Custom's computer, it was developed and is maintained by FDA. FDA's electronic screening criteria module makes the initial screening decision on every entry of foreign-origin FDA-regulated product. Virtually instantaneously after the entry is filed, the filer receives FDA's admissibility decision covering each entry, i.e., "MAY PROCEED" or "FDA REVIEW. "

Examples of FDA's need to further review an entry are products originating from a specific country or manufacturer are known to have a history of problems, FDA has no previous knowledge of the foreign manufacturer and/or product, an import alert has 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.

With the inception of the Custom's automated system (ACS), FDA's electronic screening criteria program is applied nationwide. This virtually eliminates problems such as "port shopping," e.g., attempts to intentionally slip products through one FDA port when refused by another, or to file 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 described above. The screening criteria can be set to be as specific or as broad as applicable; changes are virtually immediately effective. This capability is of tremendous value in protecting the public in the event there is a need to immediately halt specific product from entering this U.S.

### 3. Consideration Given to Information Technology

One new data element required by FDA (the FDA product code) necessitated FDA to provide nationwide training to all filers to instruct them how to build an FDA product code. At the training course, FDA provided the 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 required as many as 10,000 copies and updates to be developed and distributed. The hardcopy manual is no longer updated. (This represents another very significant reduction in paper and resources, both in the private and public sector.)

Another important benefit of the automation of the manual system is the intelligence gained (and used) as the database expands. This automated system is 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 is also of great value to the FDA personnel responsible for planning and delegating import work, e.g., what products are coming into which ports, in what quantities, manufactured by whom, coming from what country, etc. FDA previously relied on information obtained from Census and Customs records which could be up to several years old.

### 4. Identification of Information

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

### 5. Small Businesses

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 maintains "help desks" to resolve filer questions/problems.

#### 6. Less Frequent Information Collection

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, this 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 have become accustomed) FDA's admissibility decisions via the automated system. This would be very disadvantageous to importers, for whom speedy clearance saves them demurrage and other significant cost incurred when shipments are delayed for regulatory review.

#### 7. Special Information Collection Circumstances

With regards to record retention, Customs regulation 19 CFR 162.1(c) 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.

FDA's OASIS automated import entry records are to be retained 10 years--one grow year and three full fiscal years are to be kept actively on-line, and the previous six years data are kept on an archived medium (disk, CD, or tape). Other related FDA automated records and paper documents are to be retained and disposed of in accordance with instructions set forth in the FDA Staff Manual Guide, Records Management, dated February 1, 1995, and Appendix B-331 of the FDA Records Control Schedule, pages 1-103, dated December 31, 1989, and Appendix B-331 of the FDA Control Schedule, pages 100-120, dated March 21, 1986. The retention time for these records vary according to their category.

#### 8. Outside Consultation

In the **Federal Register** dated August 3, 2005 (70 FR 44656), (Attachment B) FDA published a 60 day notice requesting comments on the information collection requirements. One comment was received

The Government of Canada is concerned that the methodology used does not take into consideration the additional burden of the FDA Interim Final Prior Notice and Regulation Rules which came into effect December 2003. They urged FDA to amend the methodology used to take into consideration the additional burden associated with all requirements for providing information concerning foreign-origin FDA regulated foods, in particular, the burden resulting from the implementation of the Prior Notice and Regulation Rules under the FDA Bio-Terrorism Act of 2002.

The burden for the Prior Notice and Regulation Rules is separate from the burden reported herein. is contained in OMB Approval Number 0910-0520, OMB Expiration Date 10/31/2006.

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 Customs client representatives.

9. Payment or Gift.

No payment or gift was provided to respondents

10. Confidentiality Provisions

No assurance of confidentiality has been provided except as generally considered in review guidelines in 21 CFR 20.61.

11. Privacy

There were no questions asked of a sensitive nature.

12. Burden of Information Collection

The hour burden in the Federal Register Notice is a result of averaging and extrapolating data obtained during FDA's survey of nine (9) representative filers nationwide. For purposes of comparison of hour burden, the filers also were requested to and provided the same information with regard to filing entries manually. FDA feels this average time has remained the same.

Based on the extrapolation of data collected by FDA's survey of nine (9) filers, the total annual burden to the import community to submit information electronically for 3,709,333 ( average for calendar year 2004) separate entries is 519, 307 hours; this figure includes the time it takes filers to compile and provide documents to FDA for those entries where FDA cannot make an admissibility decision based on the electronic data alone.

For comparison purposes, using data provided by surveying the same nine (9) filers, if 3,709,333 entries were submitted via a manual, non-automated system, as was done in the past, the annual hour burden would be 578,655 hours.

Nine filers surveyed in 1996 advised there were no additional costs to provide import data electronically to FDA, as they already had equipment/software in place to enable them to provide data to Customs via the automated broker interface. Based on the survey and our knowledge on the matter, no additional software/hardware need be developed/purchased to enable filers to file the FDA data elements at the same time they file entries electronically with Customs.

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

Estimated Annual Reporting Burden <sup>1</sup>				
No. Respondents	Annual Frequency Per Response	Total Annual Responses	Hours Per Response	Total Hours
3406	1089	3,709,134	.14 hr	519,279

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

The above numbers for "Total Annual Responses" have been adjusted to eliminate disclaimed entries. Disclaimed entries are not FDA commodities.

The annual reporting burden is derived from the basic processes and procedures used in fiscal year (FY) 1995. The total number of entries submitted to the automated system in FY 2004 was 6,626,827. The total number of entries less the disclaimer entries will represent the total FDA products entered into the automated system. A total of 53 percent of all entries entered into the automated system were 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 by FDA contacting some potential respondents. Disclaimer entries are not FDA commodities.

The number of respondents is a count of filers who submit entry data for foreign-origin FDA-regulated products in FY2004.

The information dealing with total estimated annual Reporting burden to the import community will remain the same. The basic processes and procedures used in FY95 have remained the same as those used today. The exception is that the total number of entries has increased.

Due to the intricacies of building a seven-digit product code comprised of five parts, FDA made attendance at product code training course a prerequisite to filers participating in FDA's automated entry process. This course has been held nationwide, and is conducted as the need arises, e.g., filers who choose to begin participating in the automated filing program, as new filer firms are established, as a result of filer personnel changes, etc., FDA prepares announcements of upcoming courses, which Customs issues at our request via their automated broker interface.

Filers from one state have been known to travel to another to attend the course.

### 13. Cost to Respondent Resulting from the Collection of Information

None

### 14. Annualized Cost to "FDA

Salary of the FDA entry reviewer varies, however, the average salary is estimated to be GS-10 at an annual base of \$54,446. It is estimated that 154.7 Full Time Equivalent (FTEs) are required to review the importers entry notice. Therefore, the cost for salaries is \$8,422,796 per year (\$54,446 salary x's 154.7 FTE's).

The FTE number was calculated based on information provided by employees into the FDA data system.

### 15. Explanation for Change.

Due to the increase in entries of approximately 10% per year, the burden for this collection of information has increased.

### 16. Statistical Reporting.

No tabulation of the data is planned or anticipated.

### 17. Display of OMB Approval Date

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 statement identified in Item 19, "Certification for Paperwork Reduction Act Submission," of OMB Form 83-I.