SUPPORTING STATEMENT FOR

Importer' s Entry Notice

OMB No.0910-0046

Section A -Justification

1. Circumstances Necessitating Information Collection

Section 801 of the Food, Drug, and Cosmetic Act (the act) 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 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, importers were required to file manual entry(ies) on OMB-approved forms FDA 700, 701, 702 and 703 (Importer's Entry Notice) 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 USCS house box number, bill of lading number, location of goods, etc.

FDA eliminated use of the forms FDA 700 set, effective no later than FY 1996 (October 1, 1995), to reduce the paperwork burden both on the import community and FDA and to eliminate duplicity of information. FDA then developed and implemented, nationwide, an automated 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 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.

In order to make an admissibility decision for each entry, FDA needs four additional pieces of information that are not available from USCS’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 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.

All entry data to pass through a screening criteria program resident on a USCS computer. Even through this screening module resides on a USCS 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.”

Some 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, or 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," (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 the U.S.

3. Consideration Given to Information Technology

One 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.)

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 USCS issues at our request via their automated broker interface.

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 USCS records which could be 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 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 Information Collection Circumstances

With regards to record retention, USCS 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 be 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 times for these records vary according to their category.

8. Outside Consultation

In the **Federal Register** dated August 3, 2005 (70 FR 44656), 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.

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. 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 extrapolating and 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 and provided the same information with regard to filing entries manually. FDA feels this average time is the same.

Based on the extrapolation of data collected by FDA's survey of nine 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 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.

FDA estimates that there are 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. Based on the survey and our knowledge on the matter, no additional software or hardware need be developed/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 which expires 10/31/2006.

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

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

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

The "Total Annual Responses" have been adjusted to eliminate disclaimed entries. Disclaimer entries are not FDA commodities.

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 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 in FY2004. The estimated reporting burden is based on information obtained by FDA contacting some potential respondents.

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 Equivalents (FTEs) are required to review the importers entry notice. Therefore, the cost for salaries is $8,422,796 per year ($54,446 salary multiplied by 154.7 FTEs).

15. Explanation for Change.

The total burden has increased due to the increase in entries of approximately 10% per year.

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 0MB Form 83-I.