Export Certificates for FDA Regulated Products Under U.S.C. Sections 801(e) and 802
0910-0498

Supporting Statement

A. 1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA) is requesting approval from the Office of Management and Budget (OMB) for the collection of information associated with the export of products and issuance of export certificates authorized by Section 801(e) and 802 of the Federal Food, Drug and Cosmetic Act (the act).

In April 1996 a law entitled, "The FDA Export Reform and Enhancement Act of 1996" amended sections 801(e) and 802 of the act (21 U.S.C. 381(e) and 382). It was designed to ease restrictions on exportation of unapproved pharmaceuticals, biologics, and devices regulated by FDA. FDA issued a guidance for industry entitled, "Guidance for Industry: Exports and Imports Under the FDA Export Reform and Enhancement Act of 1996" to further clarify the April 1996 law. FDA's guidance for on FDA export certificates is available at http://www.fda.gov/oc/guidance/frexport.html.

Section 801(e)(4) of the act provides that persons exporting certain FDA-regulated products may request that FDA certify that the products meet the requirements of sections 801(e) or 802 or other requirements of the act. The act does not require FDA to issue certificates for food, including animal feeds, food and feed additives, and dietary supplements, or cosmetics. However, since foreign governments may require certificates for these types of products, the agency intends to continue to provide this service as resources permit.

Section 801(e)(4) of the act also provides that FDA may charge a fee of up to $175 if FDA issues a certificate within 20 days of receipt of a complete request for such a certificate. This fee may vary depending on the product type, but it will not exceed $175.

2. Purpose and Use of Information Collection

The purpose of collecting the information is to ensure that the firm will be exporting the products according to sections of the act (e.g. the firm is registered and the product(s) are listed or the device(s) are cleared for marketing for certificates to foreign governments only). Also, foreign countries put the responsibility on the FDA to ensure that the applicable statutes are met. Finally, the failure by FDA to ensure that exported products are reasonably safe and effective would have a negative effect on the export market.

The information collected is necessary to reduce the processing time for certificates to less than the 20 days as required by the statute. Without the requested information, FDA staff would need to search several databases covering many years of pre-market clearance and inspectional data. With the requested information, staff can focus immediately its data search to verify its authenticity. Any suspected case of fraud will be referred to FDA's Office of Criminal Investigations for follow up.

FDA issues six different types of certificates, each containing specific information about a product's regulatory or marketing status.

Certificate Name	Form FDA	Use	Issuing FDA Center
Certificate to Foreign Government	3613	For the export of products that can be legally marketed in the United States.	Center for Biologic Evaluation and Research (CBER); Center for Devices and Radiological Health (CDRH); Center for Veterinary Medicine (CVM)
Certificate of Exportability	3613a	For the export of products that cannot be legally marketed in the United States but meet the requirements of sections 801(e) or 802 of the act and may be legally exported.	CBER; CDRH; CVM
Certificate of a Pharmaceutical Product	3613b	For use by the importing country when considering whether to license the product in question for sale in that country. Conforms to the format established by the World Health Organization.	CBER; Center for Drug Evaluation and Research (CDER); CVM
Non-Clinical Research Use Only Certificate	3613c	For the export of non-clinical research use only product, material, component that is not intended for human use which may be marketed in, and legally exported from the United States under the act.	CBER; CDRH
Office of Cosmetics and Colors "Certificate" (Exports) Application	3613d	For cosmetic products that may be legally marketed in the United States.	Center for Food Safety and Applied Nutrition (CFSAN)
Food Export Certificate Application	3613e	For food products and dietary supplements that may be legally marketed in the United States.	CFSAN

FDA has relied on and will continue to rely on information provided by manufacturers for all types of certificates. Manufacturers are requested to state that they are in compliance with all applicable requirements of the Act, not only at the time that they submit their request to the appropriate center but also at the time that they submit the certification to the foreign government.

FDA will check all information submitted by firms in support of their certificates and any suspected case of fraud will be referred to FDA's Office of Criminal Investigations for follow up. Firms making or submitting false statements on any documents submitted to FDA may be violating the United States Code Title 18, Chapter 47, Section 1001 and be subject to penalties including up to $250,000 in fines and up to 5 years imprisonment.

3. Use of Improved Information Technology and Burden Reduction

FDA is seeking ways to reduce burdens through advances in information technology.

There are no technical or legal obstacles to the use of improved information technology to reduce the burden of reporting the information.

OMB stated in the terms of clearance for this information collection that, "FDA shall make this collection electronically submittable as soon as possible to be in compliance with the Government Paperwork Elimination Act." FDA is in the process of developing a concept paper to present to FDA's Bioinformatics Board. Funding for this system has not yet been determined; however the combined user fees collected by FDA's centers for issuing these export certificates may be sufficient to support this project. Limited resources continue to delay the progress.

4. Efforts to Identify Duplication and Use of Similar Information

FDA knows of no similar data gathered or maintained by any State or Federal agencies or other sources.

5. Impact on Small Businesses or Other Small Entities

FDA believes that its duty requires the equal application of the regulations to all enterprises. While FDA does not believe it can apply different standards with respect to statutory requirements, the Agency does provide special help to small businesses. A small business coordinator is available within each FDA Center and most FDA district offices. This coordinator is available to provide small businesses with help in dealing with FDA regulatory requirements, to ensure that they have an adequate opportunity to express their concerns and to keep FDA management apprised of how regulatory decisions might impact the small business community.

6. Consequences of Collecting the Information Less Frequently

Less frequent collection of this information would impact negatively upon FDA's ability to assure that applicable statutes are being followed before products are exported. Many foreign countries will accept FDA regulated products manufactured in the United States only because they have faith in the integrity of FDA export certificates based on current information. Collecting less information would have a negative impact on the marketability of products in foreign countries.

FDA would also have to resort to using previous certificate procedures where little information was collected from the firms to verify product and registration information through FDA databases. This, however, would increase greatly the amount of time for FDA to process the certificates and was found unacceptable by industry.

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

This information collection is consistent with the guidelines prescribed in 5 CFR 1320.5.

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

In the FEDERAL REGISTER of December 17, 2008, (73 FR 76655) FDA invited public comment on the proposed information collection. No comments were received.

9. Explanation of Any Payment or Gift to Respondents

FDA does not intend to provide any payment or gift to respondents.

10. Assurance of Confidentiality Provided to Respondents

These provisions do not permit disclosure of information that is made trade secret or commercial confidential unless that information has been previously disclosed or is permitted under the Federal Freedom of Information Act.

11. Justification for Sensitive Questions

No questions of a private or sensitive nature are asked.

12. Estimates of Annualized Burden Hours and Costs

Based on consultation with a few respondents the average time to prepare a certification request is one hour. Some firms send in requests as often as three or four times a month while others may submit only periodic requests.

FDA estimates that the annual salary cost to respondents is $611,866 (13,287 hours x $46.05). This hourly figure is estimated using the annual estimated salary of $96,100.

The estimate of burden for this collection of information is as follows:

Table 1 - ESTIMATED ANNUAL REPORTING BURDEN

Table 1. – Total Estimated Annual Reporting Burden[1]					
FDA Center	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Center for Biologics Evaluation and Research	1,501	1	1,501	1	1,501
Center for Drug	7,046	1	7,046	1	7,046

Evaluation and Research					
Center for Devices and Radiological Health	6,091	1	6,091	2	12,182
Center for Veterinary Medicine	664	1	664	1	664
Center for Food Safety and Applied Nutrition	1,794	5	8,970	2	17,940
Total	14,853		24272		39,333

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

The burden estimates were averaged based on the approximate number of requests for certificates the agency received over the past three years.

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

In addition to the costs to respondents mentioned above, Section 801(e)(4)(B) authorizes FDA to charge firms for export certificates at the rate of $175 for original certificates. Each center has its own fee structure based on resource requirements. The fees range from $100 for each original certificate and $10 for copy (CDRH) to $175 for each original certificate, $175 for a duplicate original, and $85 for each subsequent duplicate (CBER). CVM charges $175 for an original, $155 for the first copy, and $75 for each additional copy.

Costs for Certificate by Center

FDA Centers	Original	Duplicate Original	Additional Copies
CBER	$175	$175	$85
CDER	$175	$90	$40
CDRH	$100	$10	$10
CVM	$175	$155	$75

In FY 2004, approximately 2,400 original certificate requests were received from industry for which FDA charges $375,000 and approximately 8,300 additional certificate requests were received for which FDA charges $435,750. The total additional cost burden to industry for FY 2004 was $810,750.

14. Annualized Cost to the Federal Government

In FY 2008, FDA expended the time of 6 technicians, consumer safety officers, or managers (ranging from GS-4 to GS-15) on the processing of export certificates. FDA estimates that the annual salary to the agency is $381,920. (13,640 hours x $28). This hourly figure is estimated using the annual estimated salary of $57,715. In addition, $45,000 was expended for supplies, copying and other necessities. The total cost to FDA for FY 2008 was $423,500 for processing export certificates.

15. Explanation for Program Changes or Adjustments

The total annual burden increase is due to the increased number of requests for export certificates.

16. Plans for Tabulation and Publication and Project Time Schedule

The information collected will not be used for statistical purposes.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The FDA is not requesting a waiver for displaying the OMB expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

N/A

B. B. Collection of Information Employing Statistical Methods

There are no statistical methods being employed in this collection of information.