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

SUPPORTING STATEMENT

TERMS OF CLEARANCE: Previous terms of clearance stated "FDA shall make this collection electronically submittable as soon as possible to be in compliance with the Government Paperwork Elimination Act." Three years later, these forms are still not electronically submittable. Therefore, clearance is provided for 18 months. Upon resubmission, FDA should provide a timeframe under which FDA expects to come into compliance with the GPEA.

FDA'S RESPONSE TO THE TERMS OF CLEARANCE IS ATTACHED AS A SUPPLEMENTARY DOCUMENT.

A. Justification

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/RegulatoryInformation/Guidances/ucm125789.htm.

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.

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

2. Purpose and Use of the 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.

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)	3613d	For cosmetic products that may be legally marketed in the United States.	Center for Food Safety and Applied Nutrition (CFSAN)
Food Export Certificate	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 permits electronic submission of Form FDA 3613d and Form FDA 3613e on the Internet via the Certificate Application Processing (CAP) system developed by CFSAN. The agency estimates that about one hundred percent (100%) of the requests on Form FDA 3613d and Form FDA 3613e will be submitted electronically in the next three years. Phase two of FDA's plan to make this collection's forms electronically available is in progress. FDA is in the process of making the additional forms (Form FDA 3613, Form FDA 3613a, Form FDA 3613b and Form FDA 3613c) available electronically via CAP. Phase three of FDA's plan to make this collection's forms electronically available is currently in development and involves possible modification to the data elements of some of the series 3613 forms and possible use of additional electronic submission methods or portals. These modifications will be proposed in a subsequent information collection request, as additional Information Technology projects are developed.

4. Efforts to Identify Duplication and Use of Similar Information

FDA knows of no similar data gathered or maintained by any Federal agency or other source.

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 US products 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 March 31, 2010, (75 FR 16137-38) 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

12a. 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.

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	2,114	1	2,114	1	2,114
Center for Drug Evaluation	5,251	1	5,251	2	10,502

and Research					
Center for Devices and Radiological Health	6,463	1	6,463	2	12,926
Center for Veterinary Medicine	855	1	855	1	855
Center for Food Safety and Applied Nutrition (Three different product categories)	386	2	772	1.5	1,158
	247	47	11,609	2	23,218
	337	1	337	0.5	169
Total	15,653		27,401		50,942

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

The burden estimates were calculated based on the approximate number of requests for certificates the agency received in FY 2009.

12b. FDA estimates that the annual salary cost to respondents is $2,449,662 (50,942 hours x $47.78.) This hourly figure is estimated using the annual estimated salary of $99,373.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

Section 801(e)(4)(B) authorizes FDA to charge firms for export certificates at the rate of no more then $175 per original certificate. Each center has its own fee structure based on resource requirements. The fees for duplicates and additional copies range from $10 (CFSAN) to $175 (CBER.) In 2009, FDA charged approximately $ 3,107,462 in fees.

Costs for Certificate by Center

FDA Centers	Original	Duplicate Original	Additional Copies
CBER	$175	$175	$85
CDER	$175	$90	$40
CDRH	$175	$15	$15
CVM	$175	$155	$70
CFSAN	$10	$10	$10

FDA does not have available a detailed breakdown of the number of original, duplicate or additional copies of export certificates per center. Therefore, an average cost per certificate of $61.00 multiplied by the total number of respondents (50,942) was used to calculate the "Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs."

14. Annualized Cost to the Federal Government

In FY 2009, FDA expended the time of 32 technicians, consumer safety officers, or managers (FTE positions ranging from GS-4 to GS-15 and contractors) on the processing of export certificates. FDA estimates that the cost of their annual salaries and benefits to the agency is $2,904,922. In addition, $222,810 was expended for supplies, copying and other necessities. The total cost to FDA for FY 2009 was $3,127,732 for processing export certificates.

15. Explanation for Program Changes or Adjustments

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

The adjustment (increase) in "Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs" can be attributed to this cost being incorrectly reported in ICRAS with the last submission. This cost appeared in section 13 of the supporting statement but was not included with the approval as such a cost because it was not entered in ICRAS correctly. With this submission the error will be corrected.

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

There are no exceptions to the certification.