U.S. Food and Drug Administration
Export Certificates for FDA Regulated Products Under
U.S.C. Sections 801(e) and 802
OMB Control No. 0910-0498

TERMS OF CLEARANCE: Previous terms of clearance remain in effect.

Supporting Statement PART 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.

In January 2011, section 801(e)(4)(A) was amended by the Food Safety Modernization Act (FSMA) to provide authorization for export certification fees for food and animal feed.

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.

In this information collection request FDA is asking for approval of four different types of certificates, each containing specific information about a product's regulatory or marketing status.

Type of Certificate	Use
"Supplementary Information Certificate to Foreign Government Requests" "Exporter's Certification Statement Certificate to Foreign Government"	For the export of products legally marketed in the United States
"Supplementary Information Certificate of Exportability Requests" Exporter's Certification Statement Certificate of Exportability"	For the export of products not approved for marketing in the United States (unapproved products) that meet the requirements of sections 801(e) or 802 of the FD&C Act
"Supplementary Information Certificate of a Pharmaceutical Product" "Exporter's Certification Statement Certificate of a Pharmaceutical Product"	Conforms to the format established by the World Health Organization and is intended for use by the importing country when the product in question is under consideration for a product license that will authorize its importation and sale or for renewal, extension, amending, or reviewing a license
"Supplementary Information Non-Clinical Research Use Only Certificate" "Exporter's Certification Statement (Non-Clinical Research Use Only)"	For the export of a non-clinical research use only product, material, or component that is not intended for human use which may be marketed in, and legally exported from the United States under the FD&C Act

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

The agency has converted 54% of its export certificate request forms to an electronically submittable version via the Certificate Application Tracking system (eCATS). This electronic option is in addition to the paper forms available and contain the same information for collection. FDA is in the process of making Form FDA 3613, Form FDA 3613a, Form FDA 3613b and Form FDA 3613C submittable electronically for Center for Biologics Evaluation and Research and Center for Veterinary Medicine export certificate requests. 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 November 27, 2017, (82 FR 56031) 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. We have, therefore, estimated an average burden per response as indicated in the table below. The burden estimates were calculated based on the approximate number of requests for certificates the agency received in FY 2016.

Table 1 - ESTIMATED ANNUAL REPORTING BURDEN

FDA Center And FDA form	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Center for	2,651	1	2,651	1	2,651

Biologics Evaluation and Research FDA 3613 FDA 3613a FDA 3613b FDA 3613c					
Center for Devices and Radiological Health FDA 3613 FDA 3613a FDA 3613c	11,175	1	11,175	2	22,350
Center for Veterinary Medicine FDA 3613 FDA 3613a FDA 3613b	1,925	1	1,925	1	1,925
Center for Drug Evaluation and Research FDA 3613f	3,680	1	3,680	1	3,680
Total					30,606

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

12b. FDA estimates that the annual salary cost to respondents is $1,462,354 (30,606 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 than $175 per original certificate. Each center has its own fee structure based on resource requirements.

Costs for Certificate by Center

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

Estimated in Table 1, Column 4 (19,431), fees for the above four centers would total approximately $ 3,400,425 (19,431 x $175 per request).

14. Annualized Cost to the Federal Government

FDA estimates the total cost to the Federal government for processing export certificates to be approximately $3,300,000.

15. Explanation for Program Changes or Adjustments

In this ICR FDA has four adjustments in burden hours.

Adjustment #1: CBER experienced an increase in the number of export certificates issued over the past three years. The estimated annual hourly burden, formerly estimated as 2,114 hours, has increased by 537 hours to a total estimated annual hourly burden of 2,651 hours.

In addition, the Annual IC cost burden, formerly estimated as $369,950, has increased by $13,475 to a total Annual IC cost of $463,925.

	Requested	Change Due to Adjustment in Agency Estimate	Previously Approved
Annual Number of Responses for this IC	2651	537	2114
Annual IC Time Burden (Hours)	2651	537	2114
Annual IC Cost Burden (Dollars)	463925	93975	369950

Adjustment #2: CDRH experienced an increase in the number of export certificates issued over the past three years. The estimated annual hourly burden, formerly estimated as 10,528 hours, has increased by 647 hours to a total estimated annual hourly burden of 11,175 hours.

In addition, the Annual IC cost burden, formerly estimated as $1,842,400, has increased by $113,225 to a total Annual IC cost of $1,955,625 for issuing medical device export certificates.

	Requested	**Change Due to Adjustment in Agency Estimate**	**Previously Approved**
Annual Number of Responses for this IC	11175	647	10528
Annual IC Time Burden (Hours)	22350	1,296	21056
Annual IC Cost Burden (Dollars)	1955625	113225	1842400

Adjustment #3: CVM experienced an increase in the number of export certificates issued over the past three years. The estimated annual hourly burden, formerly estimated as 1,819 hours, has increased by 106 hours to a total estimated annual hourly burden of 1,925 hours.

In addition, the Annual IC cost burden, formerly estimated as $318,325, has increased by $18,8550 to a total Annual IC cost of $336,875.

	Requested	**Change Due to Adjustment in Agency Estimate**	**Previously Approved**

Annual Number of Responses for this IC	1925	106	1819
Annual IC Time Burden (Hours)	1925	106	1819
Annual IC Cost Burden (Dollars)	336875	18550	318325

Adjustment #4: CDER experienced a decrease in the number of export certificates issued over the past three years. The estimated annual hourly burden, formerly estimated as 5,251 hours, has decreased by 1571 hours to a total estimated annual hourly burden of 3,680 hours.

In addition, the Annual IC cost burden, formerly estimated as $695,758, has decreased by $51,758, to a total Annual IC cost of $644,000.

	Requested	**Change Due to Adjustment in Agency Estimate**	**Previously Approved**
Annual Number of Responses for this IC	3680	- 1571	5251
Annual IC Time Burden (Hours)	3680	- 6822	10502
Annual IC Cost Burden (Dollars)	644000	- 51758	695758

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.