UNITED STATES FOOD & DRUG ADMINISTRATION

Export Certificates for FDA Regulated Products
Federal Food, Drug, and Cosmetic Act Sections 801(e) and 802

OMB Control No. 0910-0498

SUPPORTING STATEMENT **PART A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, the agency, us or we) implementation of sections 801(e) and 802 of the Federal Food, Drug, and Cosmetic Act (FFDCA). Section 801(e)(4) of the FFDCA provides that persons exporting FDA-regulated products may request FDA to certify that the product meets the requirements of sections 801(e) or 802 or other requirements of the FFDCA. Section 801(e)(4) of the FFDCA 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.

We have developed the following forms to assist respondents in requesting FDA export certificates under sections 801(e) and 802 of the FFDCA

FDA 3613: *Supplementary Information; Certificate to Foreign Government Requests*
FDA 3613a: *Certificate of Exportability Requests*
FDA 3613b: *Certificate of Export; Supplementary Information for Pharmaceutical Product; Exporter Statement for CBER or CVM*
FDA 3613c: *Certificate of Export; Supplementary Information for Non-Clinical Research Use*
FDA 3613f: *Request for Certificate of a Pharmaceutical Product for CDER Products*
FDA 3613g: *Certificate for Device not Exported from the United States*
(FDA Forms 3613d and 3613e pertaining to food and cosmetic products are approved under OMB control no. 0910-0793)

Since last OMB review, we have revised the scope of the collection to include provisions introduced under the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) that may require supplemental information for exported product certificates. The data elements have been incorporated into our current form versions. The fact that FDA has issued an export certificate does not preclude FDA from taking appropriate regulatory action against a product covered by the certificate.

We have also developed the guidance document entitled, "*Exports and Imports Under the FDA Export Reform and Enhancement Act of 1996*" (December 1996) to assist respondents

to the information collection. The guidance summarizes and explains the basic requirements and procedures under the FDA Export Reform and Enhancement Act of 1996 (Public Law 104-134, as amended by Public Law 104-180) for exporting human drugs, animal drugs, biological products, devices, food, food additives, color additives, and dietary supplements that may not be sold or distributed in the United States. The 1996 law amended sections 801 and 802 of the Federal Food, Drug, and Cosmetic Act (the Act), as well as section 351(h) of the Public Health Service Act, simplifying the requirements for exporting unapproved human drugs, biological products, and devices. In addition, the FDA Export Reform and Enhancement Act substantially reduced the requirements for exporting unapproved new animal drugs and provided a new option for exporting unapproved devices. The guidance document is available from our website at: http://www.fda.gov/RegulatoryInformation/Guidances/ucm125789.htm.

We are therefore requesting OMB approval of the information collection associated with FDA's export certificate program, and the associated forms and guidance discussed in this supporting statement.

2. Purpose and Use of the Information Collection

FDA uses the information collection to ensure that exported products and associated certificates conform to current statutory requirements under the FFDCA. The information collection also assists foreign governments in recognizing certified information. To ensure timely processing of submissions, we have developed fillable, fileable forms as discussed above. Here we identify 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

We rely on, and will continue to rely on, information provided by manufacturers for all types of certificates. Manufacturers submit that they are in compliance with all applicable requirements of the FFDCA, not only at the time a certificate request is submitted but also at the time the certificate is submitted to the foreign government. We verify all information submitted by firms in support of certificate requests and any suspected case of fraud will be referred to our Office of Criminal Investigation for follow up as appropriate. 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

Export application certificates may be submitted electronically through our Certificate Application Tracking system (eCATS). This electronic option is in addition to the paper forms available and contain the same information for collection. We continue to make improvements to the associated forms in response to our experience with collection and informal, user feedback. More information on Export Certification is found in our Compliance Policy Guide (CPG) at Sec. 110.100 Certification for Exports (CPG 7150.01). Additional information on export certification processing for specific product areas refer to the following websites:

- For **Biological Products** visit Exporting CBER-Regulated Products to obtain a Certificate of Exportability, Certificate to Foreign Government, Certificate of a Pharmaceutical Product, or a Non-Clinical Research Use Only Certificate.
- For **Medical Devices** visit Exporting Medical Devices to obtain a Certificate of Exportability, Certificate to Foreign Government, or a Non-Clinical Research Use Only Certificate.
- For **Drug Products** visit Certificate of a Pharmaceutical Product Application Instructions to obtain a Certificate of a Pharmaceutical Product.

- For **Veterinary Products** visit Exporting - Animal Feed and Drugs to obtain a Certificate of Exportability, Certificate to Foreign Government, Certificate of Free Sale, or a Certificate of a Pharmaceutical Product.
- For **Cosmetics** visit Cosmetic Exports to obtain a General Certificate or Product Specific Certificate.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

There is no undue impact imposed on small businesses as a result of the information collection associated with FDA export certificates.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is determined by respondents seeking to obtain a benefit.

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

On September 16, 2020, we submitted an information collection request to the Office of Management and Budget (OMB) to revise certain data elements as may be applicable under CARES. Because Section 3856 of the CARES Act contained immediately effective provisions obligating FDA to review and process certification requests, we requested emergency processing by OMB under 5 CFR 1320.13 for the respective information collection and waiver of publication of a 60-day notice. Our information collection request was granted by OMB on September 29, 2020. In accordance with 5 CFR 1320.8(d)(1), we published a 30-day notice in the Federal Register of December 21, 2020 to invite comment on the burden we attribute to the information collection.

9. Explanation of Any Payment or Gift to Respondents

No gift or remuneration is provided to respondents; export certificates are issued upon satisfying the statutory information collection requirements.

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. Burden Hours:

Table 2.--Estimated Annual Reporting Burden[1]

FDA Center	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Center for Biologics Evaluation and Research	2,651	1	2,651	1	2,651
Center for Devices and Radiological Health	11,175	1	11,175	2	22,350
Center for Drug Evaluation and Research	3,680	1	3,680	1	3,680
Center for Veterinary Medicine	1,925	1	1,925	1	1,925
Total					30,606

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

Based on informal communications with respondents and our experience with the information collection we assume it takes respondents between 1 and 2 hours to complete an FDA export certificate, depending on the product being exported and as listed in the table above.

12b. Burden Costs:

We estimate annual costs to respondents by multiplying the total annual hours by an average industry wage rate of $47.78; based on an annual salary of $99,373 to cover a range of labor categories appropriate to submit certificate requests. This results in an estimated annual cost to industry of 1,462,354.68.

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

14. Annualized Cost to the Federal Government

Agency costs for the information collection are offset through associated fees for verification and administrative processing.

15. Explanation for Program Changes or Adjustments

Although we have made no adjustments in the cumulative burden hours associated with the information collection, passage of the CARES Act broadened the scope of the collection to request supplemental information for certain products. Revised forms are included in the information collection request and available on our website as discussed in this supporting statement.

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

Display of the OMB expiration date is appropriate, and FDA notes the current expiration date of its forms must be revised to reflect current OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.