EXPORT OF MEDICAL DEVICES;
FOREIGN LETTERS OF APPROVAL

OMB Control No. 0910-0264

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection helps support Food and Drug Administration (FDA) implementation of sections 801 and 802 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 and 382), which govern the import and export of FDA-regulated products and the issuance of export certificates for certain unapproved products, respectively. A medical device which is subject to, but does not comply with an applicable requirement under section 514 or section 515 of the FD&C Act, or a device which is a banned device under section 516 of the FD&C Act, or a device which is the subject of an Investigational Device Exemption (IDE) under section 520(g) of the FD&C Act, may be exported directly to any of 25 countries listed in section 802(b)(1)(a) of the without obtaining FDA authorization. In addition, section 802 permits manufacturers to export such devices to any other country that accepts the marketing authorization of one of the listed countries. Manufacturers are required to obtain FDA authorization to export to only those countries that will not accept the marketing authorization of one of the listed countries. However, if the manufacturer wishes to conduct clinical studies with an unapproved device in one of the unlisted countries, it must obtain FDA authorization for export of the device.

Our Center for Devices and Radiological Health (CDRH) determines whether exportation of a device would be contrary to the public health and safety and whether a device has the approval of the country to which it is intended for export (or, in countries that do not approve devices, whether the country has no objection to its importation) using the Export Certification Application and Tracking System (CECATS), available at: Requesting Export Certificates from CDRH. CECATS is a web-based application system for requesting export documents. This system helps facilitate certificate processing time, real-time validation of firm specific data, and status updates of requests. Using CECATS, users can make changes to an export application prior to review, upload additional documents such as mailing labels, and clone (auto populate) previously submitted application information for future export requests using the "*clone*" icon. A device that meets the criteria, and for which CDRH makes the requisite determination, will be authorized for export. Authorization for export has been delegated to the Director, Office of Regulatory Programs (ORP), CDRH, who issues approval and/or denial letters to requesters.

We are therefore requesting extension of OMB approval for the information collection provisions set forth in section 801(e) of the FD&C Act regarding foreign letters of approval for medical devices, as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The respondents to this collection of information are private sector for profit companies that seek to export medical devices. Requesters communicate (either directly or through a business associate in the foreign country) with a representative of the foreign government. The form of the communication to the foreign government is unimportant (telephone, letter, etc.), but the end result should be a letter from the appropriate office within the foreign government approving the importation of the medical device. Most foreign countries require such authorization regardless of FDA requirements. The authorization from the foreign country is used by the Office of Regulatory Programs (ORP), CDRH in determining if the foreign country has any objection to the importation of the device into their country.

3. Use of Improved Information Technology and Burden Reduction

As discussed above, the agency utilizes a web-based application to facilitate information collection. We continue to make technological enhancements as our limited resources permit.

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

We do not believe the information collection imposes undue burden on small entities. We estimate 11 percent of respondents are small businesses, however we provide resources to small businesses through the Center for Devices and Radiological Health (CDRH), Division of Industry and Consumer Education (DICE). DICE fulfills this function by providing workshops and technical and nonfinancial assistance to small manufacturers. DICE also maintains a toll-free "800" telephone number which firms may use to obtain information on complying with the regulations. The Office of Regulatory Programs Exports Team Compliance's Regulatory Policy and Systems Branch maintains a list of foreign liaisons from various countries to assist firms in obtaining approval letters from those countries.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory and regulatory requirements.

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

There are no special circumstances for this collection of information.

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

We published a 60-day notice for public comment in the *Federal Register* of 01/28/2022 (87 FR 4609), however no comments were received.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. Although the ICR collects personally identifiable information (PII), it is collected in the context of the subject individuals' professional capacity and the FDA-related work performed for the employer (e.g., point of contact at a regulated entity). We have determined that although PII is collected it is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Privacy Act do not apply. Specifically, we do not use name or any other personal identifier to retrieve records from the information collected. FDA limited the PII collected to protect the privacy of the individuals.

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden					
Activity/ FD&C Act Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Foreign letter of approval-- 801(e)(2)	36	1	36	2	72

12b. Annualized Cost Burden Estimate

We assume requests for foreign letters of approval will be satisfied by an attorney representative as follows:

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Lawyer*	72	$124	$8,928

* The estimated wage rate for a Lawyer is based on The Bureau of Labor Statistics (BLS) hourly wage rate of $62 for a lawyer (https://www.bls.gov/ooh/legal/lawyers.htm, accessed April 19, 2022). The hourly wage rate of $124

assumes a 40-hour work week and is rounded to the nearest dollar and has been doubled to account for benefits and overhead.

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

The respondent's costs of submission of a request to the foreign country for approval to import into that country, and subsequent submission of such approval to the FDA, vary and are considered operating and maintenance costs. On average, it appears that it can cost a requester approximately $125 per page of translation. From review of our records, it appears that foreign approval letters average two pages. Therefore, the estimated cost to requestors for processing a foreign approval letter is approximately $9,000 (36 submissions per year x 2 pages = 72 pages x $125 per page = $9,000).

14. Annualized Cost to the Federal Government

The annualized cost to the federal government is calculated based on the allocation of one full-time FDA employee (FTEs). We assume a loaded wage-rate of $281,225 (which is the agency's projected average cost of an FTE in CDRH including their non-pay costs*), to estimate an annual Federal cost of $281,225 for the information collection.

*Based on the Food and Drug Administration fully loaded FTE cost model (domestic) for FY 2020, as provided by agency economists.

15. Explanation for Program Changes or Adjustments

Since last OMB review and approval of the information collection, we have adjusted our estimate to reflect additional respondents, but fewer burden hours. While costs have remained constant, we noted an inadvertent calculation error was included in our *Federal Register* publications and we have corrected that error with this submission. We attribute this adjustment to improved efficiencies in processing requests.

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

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

The OMB expiration date will be displayed as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.