U.S. Food and Drug Administration
Export of Medical Devices; Foreign Letters of Approval

OMB Control Number 0910-0264

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

FDA is requesting approval from the Office of Management and Budget (OMB) for the collection of information from the public associated with the export of medical devices as indicated in Section 801(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

A medical device which is subject to, but does not comply with an applicable requirement under Section 514 or Section 515, or a device which is a banned device under Section 516, 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 FD&C Act 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. This document discusses the materials a requester must submit in a request to FDA to obtain FDA authorization for export of the device.

The Center for Devices and Radiological Health (CDRH) will determine, on the basis of the submitted information, whether exportation of the device would be contrary to the public health and safety and whether the 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). A device that meets the stated 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 Compliance (OC), CDRH, who issues approval and/or denial letters to requesters.

Requesters communicate (either directly or through a business associate in the foreign country) with a representative of the foreign government to which they seek exportation, and written authorization must be obtained from the appropriate office within the foreign government approving the importation of the medical device. An alternative to obtaining written authorization from the foreign government is to accept a notarized certification

from a responsible company official in the United States that the product is not in conflict with the foreign country's laws. This certification must include a statement acknowledging that the responsible company official making the certification is subject to the provisions of 18 U.S.C. 1001. This statutory provision makes it a criminal offense to knowingly and willingly make a false or fraudulent statement, or make or use a false document, in any manner within the jurisdiction of a department or agency of the United States.

Section 801(e)(2) of the FD&C Act requires that the Food and Drug Administration (FDA) provide authorization for the exportation of an unapproved Class III device, or an unapproved device subject to a mandatory standard, if the exportation is not contrary to the public health and safety and it has the approval of the foreign country to which it is intended for export.

Section 802 of the FD&C Act permits export of such devices to 25 listed countries without obtaining FDA authorization. While section 802 requires that manufacturers maintain in their files written marketing authorization from the importing country, this is not considered to be an extra burden, as all of the listed countries do require some type of marketing clearance (i.e., in the EU, an CE mark is required).

Manufacturers communicate (either directly or through a business associate in the foreign country) with a representative of the foreign government to apply for written authorization to import and market the subject devices.

FDA is requesting approval from the Office of Management and Budget (OMB) for the collection of information from the public associated with the export of medical devices as indicated in section 801(e) of the FD&C Act.

A medical device which is subject to, but does not comply with an applicable requirement under Section 514 or Section 515, or a device which is a banned device under Section 516, 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 FD&C Act 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 now 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.
In order to obtain such authorization, a requester must submit a request to FDA and include the following information:

(a) Description of the device intended for export;
(b) The status of the device in the United States, that is, whether it is investigational, banned, etc.

(c) If the device has an approved IDE, the approval date and IDE number; or,

(d) Supporting material to demonstrate that export of the device will not be contrary to the public health and safety; and

(e) A letter or supporting document from the appropriate official of the country to which the device is intended for export (or, if the country is aware of the export, a member of the company intending to export the device), that the device has the approval of the country, or, in countries that do not approve devices, that there is no objection to its importation. The statement from the foreign official must be in the English language, or a certified translation must accompany the request.

An alternative to the foreign government's letter is the acceptance of a notarized certification from a responsible company official in the United States that the product is not in conflict with the foreign country's laws. This certification must include a statement acknowledging that the responsible company official making this certification is subject to the provisions of 18 U.S.C. 1001, which makes it a criminal offense to knowingly and willfully make a false or fraudulent statement, or make or use a false document, in any matter within the jurisdiction of a department or agency of the United States.

The Center for Devices and Radiological Health (CDRH) will determine, on the basis of the above information, whether exportation of the device would be contrary to the public health and safety and whether the 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). A device that meets the stated 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 Compliance (OC), CDRH, who issues approval and/or denial letters to requesters. A concurrent copy of an approval letter will be sent to the responsible government office listed on CDRH's Foreign Liaison List.

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 Compliance (OC), 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

Utilization of computers and word processors has greatly reduced the time needed to compile, submit and maintain the required documents. FDA is continuously seeking other ways through advances in information technology to reduce burdens. At the present time, and considering the small number of requests being received, there seems to be no other more efficient way to obtain the needed information from the foreign countries.

These documents must be translated from the foreign country's language and most need to be notarized. Also, a large amount of safety data often accompanies each export request. For these reasons, no electronic submissions are normally received by FDA.

4. Efforts to Identify Duplication and Use of Similar Information

FDA is the only agency with the regulatory authority to collect the information required in this information collection. There is no other collection of this information that we are aware of made by any other agency. No formal efforts have been made to identify duplication; however, at meetings with other Federal agencies, questions related to this issue have not identified any duplication.

5. Impact on Small Businesses or Other Small Entities

The respondents to this collection of information are for profit businesses that seek to export medical devices. The requirements imposed by this collection are applied equally to all firms regardless of the firm's size. Approximately 11 percent of the respondents are small businesses. FDA aids small businesses by providing guidance and information 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 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

Respondents submit the required information occasionally. The written authorization from the foreign country is used by the Office of Compliance, CDRH, in determining if the foreign country has any objection to the importation of the device into their country. When Congress crafted section 801(e)(2) of the FD&C Act, it recognized that each device may present to each foreign country unique issues of safety. Consequently, each letter of authorization from a foreign country is specific to a device. If approval letters from foreign governments were not submitted by the requesting firm, CDRH would then have had to contact various embassies (via telephone, for example) to seek their approval, which would be time consuming and costly. If this information were collected less frequently it would not satisfy the statutory requirement of section 801(e)(2) of the FD&C Act, and could result in exposing citizens of foreign countries to a potential health risk. There are no legal obstacles to reduce the burden.

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

   In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the FEDERAL REGISTER of March 11, 2019 (84 FR 8727). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

   There is no payment or gift provided to respondents of this information collection.

10. Assurance of Confidentiality Provided to Respondents

    This ICR collects personally identifiable information (PII). PII collected is exporting company representative's name, title, phone number and, in some cases, email address. The respondents to this collection of information are companies that seek to export medical devices.

    FDA further determined that although PII is collected the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, FDA does not use name or any other personal identifier to routinely retrieve records from the information collected. FDA also minimized the PII to be collected to protect the privacy of the individuals.

    In preparing this Supporting Statement, FDA staff consulted with the FDA Privacy Office to ensure appropriate handling of information collected. FDA minimized the PII to be collected to protect the privacy of the individuals.

    Confidentiality of data and disclosure are governed by the Freedom of Information Act (FOIA) (5 U.S.C. 552). Under FOIA, 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)). One such provision, 5 U.S.C. 552(b)(4), exempts "trade secrets and commercial or financial information that is privileged or confidential" from the requirement of public disclosure. Section 520(c) of the FD&C Act prohibits FDA from disclosing any information exempted from public disclosure under 5 U.S.C. 552(b)(4). Part 20 of FDA's regulations (21 CFR Part 20) sets forth FDA's general policy concerning public availability of FDA records.

11. Justification for Sensitive Questions

    The information required by this collection does not include questions about sexual behavior, attitude, religious beliefs, or other matters which are commonly considered private or sensitive in nature.

12. Estimates of Annualized Burden Hours and Costs

    12a. Annualized Hour Burden Estimate

FDA's estimate of the reporting burden is based on the experience of FDA's medical device program personnel.

FDA estimates the burden of this collection as follows:

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)	33	1	33	3	99

12b. Annualized Cost Burden Estimate

We expect that the agreement and labeling requirements will be satisfied by regulatory affairs professionals. We expect that the recordkeeping requirements will be met by clerical workers.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Regulatory Affairs Professional*	99	$72	$7,128

*The estimated wage is based on The Regulatory Affairs Professional Society (RAPS) average total compensation for all U.S. based regulatory professionals at all levels, $150,422 per year (The Regulatory Affairs Professional Society (RAPS), "2016 Scope of Practice & Compensation Report for the Regulatory Profession," p. 11, downloaded from https://www.raps.org/careers/scope-of-practice-survey on 10/15/18). The hourly wage rate of $72 assumes a 40-hour work week and is rounded to the nearest dollar.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/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 $8,250 (33 submissions per year x 2 pages = 66 pages x $125 per page = $8,250).

14. Annualized Cost to the Federal Government

The annualized cost to the federal government will be the cost of two full time FDA employees (FTEs). Based on a cost of $270,305 per position (which is the agency's projected average cost of an FTE in CDRH including their non-pay costs*), the estimated annual Federal cost is $540,610.

*Based on the Food and Drug Administration fully loaded FTE cost model (domestic) for FY 2018, as provided by agency economists.

15. Explanation for Program Changes or Adjustments

We have adjusted our burden estimate by decreasing the number of respondents by 5, which has resulted in a corresponding decrease of 15 hours to the currently approved hour burden and $1,250 to the total operating and maintenance costs. This adjustment is based on a decrease in the number of submissions we received over the last few years.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no plans to publish this collection of information for statistical use.

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

FDA will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.