SUPPORTING STATEMENT
FOR
Export of Medical Devices - Foreign Letters of Approval
Federal Food, Drug, and Cosmetic Act Section 801(e)(2) (21 U.S.C. 381(e)(2))
OMB No. 0910-0264

A. JUSTIFICATION

Section 801(e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 381(e)(2)) (Attachment A) 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 FDA Export Reform and Enhancement Act of 1996 permits export of such devices to 25 listed countries without obtaining FDA authorization (Attachment B). 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.

1. Circumstances Making the Collection 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 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 act (see attachment C) may be exported directly to any of 25 countries listed in section 802(b)(1)(a) of the FDA Export Reform and Enhancement Act of 1996 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

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 OC, CDRH in determining if the foreign country has any objection to the importation of the device into their country.

3. Use of Information Technology and Burden Reduction

Utilization of computers and word processors have 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, and because many foreign countries are not very sophisticated in the creation of electronic documents, electronic submissions are normally not 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 Business or Other Small Entities

The requirements imposed by this collection are applied equally to all firms regardless of the firm's size. FDA aids small businesses by providing guidance and information through the Division of Small Manufacturers, International, and Consumers Assistance (DSMICA), Office of Health Industry Programs, CDRH. FDA's DSMICA fulfills this function by providing workshops and technical and nonfinancial assistance to small manufacturers. DSMICA 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

The written authorization from the foreign country is used by OC, 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 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 have been time consuming and costly. If this information were collected less frequently it would not satisfy the intent of section 801(e)(2) of the act, and could result in exposing citizens of foreign countries to a potential health risk.

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

The collection requirement for the letter of foreign approval is consistent with 5 CFR 1320.5.

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

Notice has been published in the Federal Register on September 22, 2006 (71 FR 55487) soliciting comments on this information collection prior to its submission to OMB as required by 5 CFR 1320.8(d)

(see Attachment D). In response to that notice, no comments were received.

The FDA has had routine contact with industry on the subject of medical device exports. These contacts have been in the form of phone conversations, correspondence, and oral presentations to the Food and Drug Law Institute (FDLI), the Advanced Medical Technology Association (AdvaMed) and the Regulatory Affairs Professional Society (RAPS). These are very worthwhile for both industry and government staff because they have provided direct interaction and valuable understanding of medical device issues by both parties.

During the past year, FDA has been in contact with several requestors for Section 801(e)(2) export permits in which FDA requires the requestor to obtain a letter of approval from the foreign country.

9. Explanation of any Payment of Gift to Respondents

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

10. Assurance of Confidentiality Provided to Respondent

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 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 of 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. Estimate of Hour Burden Including Annualized Hourly Costs

FDA estimates the burden of this collection of information as follows:

Estimated Annual Reporting Burden[1]						
Statute	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Operating and Maintenance Costs	Total Hours
Section 801(e)(2) of the Federal, Food, Drug, and Cosmetic Act	25	1	25	2.5	$6,250	62.5

[1]There are no capital costs associated with this collection of information.

These estimates are based on the experience of FDA's medical device program personnel. FDA staff calculated that the total cost to respondents for completing the requirements of this information collection is estimated to be $1,400. In estimating the total cost for this program, FDA looked at wage rates reported for regulatory affairs professional Society on a variety of web sites. It appears that the average salary for regulatory affairs professionals is about $92,000. FDA estimates, therefore that the total estimated burden cost to industry for reporting relating to this information collection will be $2,750, which is the total number of hours expended (62.5) multiplied by the average wage rate of $44 per hour.

13. Estimate of the Other Total Annual Cost Burden to Respondents or Recordkeepers

There are no capital costs associated with this collection of information. In addition, 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 "other" estimated cost to requestors for processing a foreign approval letter is approximately $6,250 (25 submissions per year x 2 pages = 50 pages x $125 per page = $6,250).

14. Annualized Cost to the Federal Government

For FDA, the review of approval letters from foreign governments is only a small part of the processing of an authorization to export a medical device under Section 801 (e) of the act. FDA estimates that 10 percent of two technician's time is needed to review approval letters from foreign countries for a total 416 hours. The average cost per FTE is estimated at $116,000. This annual cost further breaks down to approximately $55 per hour. Therefore the average cost for the government to process these foreign

approval letters is estimated at $22,880 per year.

15. Explanation of Program Changes or Adjustment

The increase in burden hours (adjustment),is a result of the number of respondents increasing from 20 to 25.

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

Currently, CDRH is not requesting an exemption for display of the OMB expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

Currently, CDRH is not requesting an exception to Certification for the Paperwork Reduction Act Submissions.

19. Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement identified in item 19 of OMB Form 83-I.