4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-2817]

Medical Devices; Export Certificates; Food and Drug Administration Export Reform and Enhancement Act of 1996; Certification Fees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revised fees the Agency will assess for issuing export certificates for devices. The FDA Export Reform and Enhancement Act of 1996 (EREA) provides that any person who exports a device may request FDA certify in writing that the exported device meets certain specified requirements. It further provides that FDA shall issue such a certification within 20 days of the receipt of a request for such certification and that FDA may charge up to $175 for each certification that is issued within the 20 days. Since February 2003, FDA's costs to process the device certificates have increased; however, the export certificate fee for subsequent certificates has not changed. Because of the increase, FDA is raising the fees for subsequent certificates, from the current fee of $15 to $85, and revising the formula used to calculate the number of original and subsequent device export certificates issued. These changes are necessary to ensure that the program remains self-sustaining and to cover FDA's increased costs, which are currently being covered by

appropriated funds. Further, this document explains the costs associated with the export certification program for devices.

DATES: The fees described in this document for export certificates for devices will be effective September 1, 2015.

ADDRESSES: You may submit comments by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

• Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

• Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Docket No. FDA-2015-N-2817. All comments received may be posted without change to http://www.regulations.gov, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read comments received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Leila M. Lawrence, Office of Compliance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993-0002, 301-796-7400, Option 3, FAX 301-847-8129.

SUPPLEMENTARY INFORMATION:

I. Background

The EREA became law on April 26, 1996 (Pub. L. 104-134, amended by Pub. L. 104-180). The principal purpose of this law is to expedite the export of FDA regulated products, both approved and unapproved, through amendments to sections 801(e) and 802 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 381(e) and 382). Section 801(e)(4) of the FD&C Act provides that any person who exports a drug, animal drug, or device may request that FDA certify in writing that the exported drug, animal drug, or device meets the requirements of sections 801(e) or 802 of the FD&C Act or other applicable requirements of the FD&C Act. Upon a showing that the product meets the applicable requirements, the law provides that FDA shall issue export certification within 20 days of the receipt of a request for such certification. It also allows FDA to collect fees of up to $175 for each certificate that is issued within the 20-day period. The focus of this notice is on both the fee charged per subsequent export certificate and how the Center for Devices and Radiological Health (CDRH) calculates the number of original and subsequent certificates issued.

The original notice on the EREA fees for export certificates was published in the Federal Register on November 6, 1996 (61 FR 57445), and became effective October 1, 1996. A subsequent notice, published in the Federal Register on February 11, 2003 (68 FR 6925), established CDRH's intent to charge the maximum fee of $175 for the first certificate and $15 for

all subsequent certificates issued for the same product(s) in the same request. Since February 2003, an updated resource review within CDRH has identified that recoverable costs of the device export certifications have increased. Accordingly, the fees have been recalculated so that the aggregate amount of fees collected will meet the current and future aggregate costs to issue device export certificates.

II. Agency Costs and Fees to be Assessed for Export Certificates

The costs of the export certification program for devices have grown since fiscal year 2003 (FY 03); however, the export certificate fee for subsequent certificates has not changed. Moreover, FDA has allowed multiple devices to be included in a single certificate rather than requiring that each device have a separate certificate for which a fee is charged. The increased costs in the export certification program for devices are attributable to two major areas: (1) The increased volume of requests for certificates and (2) the increase in payroll costs over the past 12 years. These two cost areas account for the major differences between FY 03 and this current year.

The volume of requests for certificates has increased by 369 percent since FY 1997 and 107 percent since FY 2003. Hence, the export certificate program staff size has increased to accommodate this increased volume of requests. Table 1 shows the increase in certificates from FY 97 to FY 14:

Table 1.--Number of Export Certificates From Fiscal Year 1997 to Fiscal Year 2014

Fiscal Year (FY)	Total Certificates
FY 1997	11,140
FY 2001	23,737
FY 2003	25,236
FY 2012	49,916
FY 2013	50,612
FY 2014	52,193

The cost of the export certification program for devices in FY 14 is $5,735,270 for payroll and operating expenses.

The four recoverable cost categories for preparing and issuing export certificates are:

- Direct personnel for research, review, tracking, writing, and assembly;
- purchase of equipment and supplies used for tracking, processing, printing, and packaging (recovery of the cost of the equipment is calculated over its useful life);
- billing and collection of fees; and
- overhead and administrative support.

As previously mentioned in this document, FDA may charge up to $175 for each certificate. Certificates for some classes of products cost the Agency more than $175 to prepare. Subsequent certificates issued for the same product(s) in response to the same request generally cost the Agency less than $175. However, due to the increase in payroll and operating expenses, the fee for issuing subsequent certificates for the same product(s) in response to the same request is being raised from the current fee of $15 to $85. Since the inception of the export certification program in 1996, this is only the second increase of the device export certificate fee under EREA. In addition, FDA is revising its formula for calculating the number of original and subsequent certificates issued.

The following fees will be assessed starting September 1, 2015, for device export certificates:

Table 2.--Fees for Original and Subsequent Export Certificates

Type of Certificate	Fee (dollars)
Original certificates (may be multiple in number)[1]	175
All subsequent certificates issued for the same product(s) in response to the same request[1]	85

[1]As calculated under formula.

Under its formula for calculating applicable fees, CDRH has allowed multiple devices to be included in a single certificate rather than requiring that each device have a separate certificate for which a fee is charged. While CDRH will continue to allow multiple devices to be included in a single certificate, it is revising the formula by which the number of original device export certificates (at $175 per certificate) and subsequent certificates (at $85 per certificate) will be calculated. The number of original and subsequent device export certificates will be calculated using a revised formula that sets the maximum pages per certificate to 25 pages (the certificate page and a maximum of 24 pages for any attachments). Previously, the maximum number of pages was 50. If the request is more than 25 pages, then the total number of pages created by the request is divided by 25 and that number will be the number of original certificates that will be charged at $175 and the remaining number of subsequent certificates will be charged at $85 each. For example, if you request 15 certificates and each certificate has 12 attachment pages plus the certificate page that means each certificate is 13 pages, and your request will generate 195 pages in all. This number of pages is divided by 25 and that equals 7.8, which is rounded to 8. Therefore, you will be charged for 8 original certificates at $175 each and 7 subsequent certificates at $85 each. Please note the maximum number of attachment pages is 24 pages. If you have more than 24 pages you will need to split the request into two or more requests.

III. Request for Comments

Although the EREA does not require FDA to solicit comments on the assessment and collection of fees for export certificates, FDA is inviting comments from interested persons in order to have the benefit of additional views.

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

IV. The Paperwork Reduction Act of 1995

This notice refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in sections 801(e) and 802 of the FD&C Act have been approved under OMB control number 0910-0498.

Dated: August 13, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-20429 Filed: 8/18/2015 08:45 am; Publication Date: 8/19/2015]