

the 20 days. FDA's costs to process the device certificates have increased since the inception of the export certification program for devices. Because of the increase, FDA is raising the fees for device export certificates accordingly. This document explains the costs included in the export certification program for devices. This is the first increase of the device export certificate fee under the EREA since the initial fee was established in 1996.

**DATES:** The fees described in this document for export certificates for devices will be effective March 1, 2003. Submit written or electronic comments by March 13, 2003.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Leila M. Craddock, Office of Compliance, Center for Devices and Radiological Health (HFZ-305), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301-827-4555, ext. 110, FAX 301-594-4715.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

The EREA became law on April 26, 1996 (Public Law 104-134, amended by Public Law 104-180, August 6, 1996). 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 act) (21 U.S.C. 381(e) and 382). Section 801(e)(4) of the 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 section 801(e) or 802 of the act, or other applicable requirements of the 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 export certificates issued by the Center for Devices and Radiological Health (CDRH).

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. An updated

resource review within CDRH has identified that recoverable costs of the device export certifications have increased since October 1996. Accordingly, the fees have been recalculated so that the aggregate amount of fees collected will meet the 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 1997 (FY 97), while the export certificate fee has not changed. The increased costs in the export certification program for devices are attributable to two major areas: (1) The volume of requests for certificates and (2) the increase in payroll costs over the past 6 years. These costs account for the major differences between FY 97 and the current year.

The volume of requests for certificates has increased by 100 percent since FY 97. In order to meet this increased volume of requests, the staff size has grown accordingly. In addition, CDRH's average salary has increased by 37 percent during the same time period. Table 1 of this document shows the increase in certificates from FY 97 to FY 02 (the number of certificates for 2002 was estimated):

TABLE 1.—NUMBER OF EXPORT CERTIFICATES FROM FISCAL YEAR 1997 TO FISCAL YEAR 2002

| Fiscal Year (FY) | Total Certificates  |
|------------------|---------------------|
| FY 97 .....      | 11,140              |
| FY 98 .....      | 17,107              |
| FY 99 .....      | 18,954              |
| FY 00 .....      | 21,292              |
| FY 01 .....      | 23,737              |
| FY 02 .....      | 23,000 <sup>1</sup> |

<sup>1</sup> Estimated.

The estimated costs of the export certification program for devices in FY 03 are: \$533,000 for payroll and \$267,000 for operating expenses. There are four recoverable cost categories for preparing and issuing export certificates. They are:

1. Direct personnel for research, review, tracking, writing, and assembly;
2. 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;
3. Billing and collection of fees; and
4. Overhead and administrative support.

As mentioned previously in this document, the agency 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. The fee for all subsequent certificates for the same product(s) issued in response to the same request reflects reduced agency costs for preparing those certificates.

The following fees will be assessed starting March 1, 2003, for device export certificates:

TABLE 2.—FEES FOR FIRST AND SUBSEQUENT EXPORT CERTIFICATES

| Type of Certificate   | Fee (dollars) |
|---|---------------|
| First certificate   | 175           |
| All subsequent certificates issued for the same product(s) in response to the same request. | 15            |

The fee for issuing the first export certificate for a device product is now at the maximum allowable amount. This fee is now consistent with the export certification fees assessed since FY 97 by all other FDA centers who provide export certification. The fees for issuing subsequent certificates continue to differ among the centers, based on varying costs. The agency expects this new fee schedule for device export certificates to remain constant for at least several years. However, if there is an increased cost to the agency in issuing device export certificates, the fee for subsequent certificates for device products may be increased in the future.

##### III. Request for Comments

Although the EREA does not require that FDA 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 to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two hard copies of any written comments, except that individuals may submit one hard copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.