

import operations. Therefore, the recordkeeping burden was calculated as the time required for the 10 percent of firms that may not currently be maintaining this documentation to develop and maintain documentation, such as batch records and inventory records. For firms that do not maintain documentation, such as batch records and inventory records, as part of their normal manufacturing operations, it was estimated that with \$500 or less, the necessary software and hardcopy filing systems could be obtained to implement a system.

### III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

### IV. Electronic Access

An electronic version of this draft guidance is available on the Internet at <http://www.cfsan.fda.gov/guidance.html>.

Dated: July 14, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 03-18634 Filed 7-22-03; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2003D-0282]

#### Guidance for Industry and FDA Staff; Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions [510(k)s] for Reprocessed Single-Use Medical Devices; Availability; Correction

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of July 8, 2003 (68 FR 40679). The document announced the availability of a guidance entitled

“Guidance for Industry and FDA Staff; Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions [510(k)s] for Reprocessed Single-Use Medical Devices; Availability.” The document published with the incorrect docket number. This document corrects that error.

#### **FOR FURTHER INFORMATION CONTACT:**

Joyce A. Strong, Office of Policy and Planning (HF-27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7010.

**SUPPLEMENTARY INFORMATION:** In FR Doc. 03-17135, appearing on page 40679 in the **Federal Register** of July 8, 2003, the following correction is made:

1. On page 40679, in the first column, in the heading of the document, “[Docket No. 2003D-0232]” is corrected to read “[Docket No. 2003D-0282]”.

Dated: July 17, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 03-18689 Filed 7-22-03; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

#### New Products and Updated Fee Schedule for National Flood Insurance Program Map and Insurance Products

**AGENCY:** Federal Emergency Management Agency (FEMA), Emergency Preparedness and Response Directorate, Department of Homeland Security.

**ACTION:** Notice.

**SUMMARY:** This Notice contains several new products and the updated fee schedule for processing requests for the National Flood Insurance Program (NFIP) map and insurance products available through the FEMA Map Service Center (MSC). The changes in the fee schedule include two new products and will allow FEMA to reduce further the expenses to the NFIP by recovering more fully the costs associated with producing, retrieving, and distributing particular NFIP map and insurance products.

**DATES:** The updated fee schedule is effective for all requests dated, August 1, 2003, or later.

#### **FOR FURTHER INFORMATION CONTACT:**

Kathy L. Miller, Acting Chief, Information Exchange and Program Evaluation Branch, Mitigation Division, 500 C Street, SW., Washington, DC

20472; by telephone at (202) 646-3316 or by facsimile at (202) 646-4596 (not toll-free calls), by e-mail at [Kathy.Miller@DHS.GOV](mailto:Kathy.Miller@DHS.GOV).

#### **SUPPLEMENTARY INFORMATION:**

Throughout this Notice, we use “we,” “our,” and “us” to refer to FEMA.

This Notice contains an updated fee schedule to include two new products available through the MSC.

**Effective Date.** The updated fee schedule is effective for all written requests, on-line internet requests made through the FEMA Flood Map Store, and all telephone requests received on or after August 1, 2003.

**Evaluations Performed.** To develop the revised fee schedule for the new products, we first evaluated the actual costs incurred at the MSC for producing, retrieving, and distributing these products. We then analyzed historical sales, cost data, and product unit costs for unusual trends or anomalies; analyzed the effect of program changes, new products, technology investments, and other factors on future sales and product costs. The products covered by this Notice are discussed below.

**Periodic Evaluation of Fees.** As indicated in the Notice, published at 67 FR 13764, March 26, 2002, a primary component of the fees is the prevailing private sector rates charged to FEMA for labor and materials. Because these rates and the actual production, retrieval, and distribution costs may vary from year to year, we will evaluate the fees periodically and publish a revised fee schedule, when appropriate, as a notice in the **Federal Register**.

#### **Fee Schedule for Requests for Map and Insurance Products**

The MSC distributes a variety of NFIP map and insurance products to a broad range of our customers, including Federal, State, and local government officials; real estate professionals; insurance providers; appraisers; builders; land developers; design engineers; surveyors; lenders; homeowners; and other private citizens. Specifically, the MSC distributes the following products:

- Paper (printed) copies of Flood Hazard Boundary Maps (FHBMs);
- Paper (printed) copies of Flood Insurance Rate Maps (FIRMs);
- Paper (printed) copies of Digital Flood Insurance Rate Maps (DFIRMs);
- Paper (printed) copies of Flood Insurance Study (FIS) reports, including the narrative, tables, Flood Profiles, photographs, and other graphics;
- Paper (printed) copies of Flood Boundary and Floodway Maps (FBFMs), when they are included as an exhibit in the FIS;

- Digital Q3 Flood Data files, which FEMA developed by scanning the published FIRM and vectorizing a thematic overlay of flood risks;
- Digital Q3 Flood Data files for Coastal Barrier Resource Areas (CBRA Q3 Flood Data files);
- Community Status Book, which is a report generated by FEMA's Community Information System database that provides pertinent map status information for all identified communities;
- Flood Map Status Information Service (FMSIS), through which FEMA provides status information for effective NFIP maps;
- Letter of Map Change (LOMC) Subscription Service, through which FEMA makes certain types of LOMCs available biweekly on CD-ROM;
- NFIP Insurance Manual (Full Manual), which provides vital NFIP information for insurance agents nationwide;
- NFIP Insurance Manual (Producer's Edition), which is used for reference and training purposes;
- Community Map Action List (CMAL), which is a bimonthly list of communities and their NFIP status codes;

- Maps on the Web—raster images of the FIRMs and Floodways in TIFF format;
- FIS on the Web—raster images of FIS in PDF format;
- Maps on CDs—includes only the raster images of the maps and can be purchased by panel or in community, county, or State kits;
- F-MIT Light on the Web—a free downloadable flood map image view tool, to be used in conjunction with viewing TIFF images, that supports panning, zooming, and creating a “firmette”. A firmette is a user-defined “cut-out” section of the map at 100% map scale designed for printing on a standard office printer;
- F-MIT Light on CD—same as F-MIT Light on the Web, designed for use with the Flood Map CD without a Database; and
- FEMA's *Guidelines and Specifications for Flood Hazard Mapping Partners on CD*: This document combines previous FEMA publications, guidance documents, and memorandums regarding Flood Hazard Mapping. The Guidelines reflect recent changes to processes and products associated with the implementation of the Map Modernization Program,

including the Cooperating Technical Partners initiative, new Project Scoping procedures, and DFIRM specifications.

The MSC is now adding two new products, which are denoted by an asterisk in the table. The following is a description of the MSC's new products:

- Community or County Databases—a digital version of the maps that is designated for use with Geographic Information Systems (GIS) software to allow users to access, view, and analyze mapping information using specialized data; and
- FMIT Pro on CD—a view and address look up tool designed for use with the community or county databases.

For more information on the map and insurance products available from the MSC, we invite interested parties to visit our MSC Web site at <http://www.msc.fema.gov/>.

There are no changes in the processing fees or shipping costs for any of the other products that the MSC distributes. Federal, State, and local governments continue to be exempt from paying fees for the map products. The fee schedules for the current and new products are shown in the table below.

Description of product of service	Fee	Shipping charge
<b>Paper Products:</b>		
FHBM, FIRM, DFIRM, or FBFM (floodway) panels.	\$2.00 per map panel .....	\$0.37 per panel for the first 10 panels plus \$0.03 for each additional panel.
FIS (not including FBFM panels that are included as exhibit).	\$5.00 per FIS volume plus \$2.00 per floodway map.	\$4.00 for the first study volume plus \$0.40 for each additional study.
Hurry Charge-Added to regular charge .....	\$33.00 .....	N/A.
<b>Internet Products (products downloadable from the web):</b>		
FHBM, FIRM, DFIRM, or FBFM (floodway) panels.	\$1.50 per map panel .....	None.
FIS .....	\$4.00 per study plus \$1.50 per floodway map	None.
F-MIT Light (view tool for map images) on the web.	Free .....	Not Applicable.
* F-Mit Pro (Viewtool & address look-up) ..	\$30.00 .....	Not Applicable.
FIRMette (A user defined portion of the FIRM printable on a desktop printer).	Free Viewing and downloading .....	Not Applicable.
<b>CD Products:</b>		
FHBM, FIRM, DFIRM, or FBFM (floodway) panels.	\$1.50 per map panel .....	\$3.65 for the first 4 CD-ROMs plus \$0.10 for each additional CD-ROM.
* Community or County Database .....	\$10.00 per database .....	\$3.65 for the first 4 CD-ROMs plus \$0.10 for each additional CD-ROM.
FIS .....	\$4.00 per FIS volume plus \$1.50 per floodway map.	\$3.65 for the first 4 CD-ROMs plus \$0.10 for each additional CD-ROM.
* F-MIT Light (view tool for map images) ..	Free .....	\$3.65.
* F-MIT Pro (view tool & address look-up)	\$30.00 .....	\$3.65.
<b>Other Products:</b>		
Q3 Flood Data Files .....	\$50.00 per CD-ROM .....	\$3.65 for the first 4 CD-ROMs, plus \$0.10 for each additional CD-ROM in the same order.
CBRA Q3 Flood Data Files .....	\$50.00 per CD-ROM or \$200.00 for all 5 Q3 CDs.	\$3.65 for the first 4 CD-ROMs, plus \$0.10 for each additional CD-ROM in the same order.
Community Status Book (Individual Orders).	\$2.50 per State \$20.50 for entire U.S .....	\$1.00 per State \$4.26 for entire U.S.
Community Status Book (Annual Subscription).	\$50.00 per State \$250.00 for entire U.S .....	Not applicable.

Description of product of service	Fee	Shipping charge
FMSIS (Individual Orders) .....	\$13.00 per State \$38.00 for entire U.S .....	3.65 for the first 4 CD-ROMs, plus \$0.10 for each additional CD-ROM in the same order.
FMSIS (Annual Subscription) .....	\$148.00 per State \$419.00 for entire U.S .....	Not applicable.
LOMC Subscription Service (Individual Orders).	\$85.00 per issue .....	\$3.65 for the first 4 CD-ROMs, plus \$0.10 for each additional CD-ROM in the same order.
LOMC Subscription Service (Annual Subscription).	\$2,000.00 .....	Not applicable.
NFIP Insurance Manual (Full Manual) .....	\$25.00 per subscription for complete manual	Not applicable.
NFIP Insurance Manual (Producer's Edition).	\$15.00 per subscription .....	Not applicable.
FEMA's Guidelines and Specifications for Flood Hazard Mapping Partners on CD-ROM.	\$2.60 .....	\$3.65.

**Payment Submission Requirements**

Fee payments for non-exempt requests must be made to us in advance of services being rendered. These payments shall be made in the form of a check, a money order, or by a credit card payment. Checks and money orders must be made payable, in U.S. funds, to the *National Flood Insurance Program*.

We will deposit all fees collected to the National Flood Insurance Fund, which is the source of funding for providing these services.

**Anthony S. Lowe,**

*Mitigation Division Director, Emergency Preparedness and Response Directorate.*

[FR Doc. 03-18652 Filed 7-22-03; 8:45 am]

**BILLING CODE 6718-04-P**

**DEPARTMENT OF THE INTERIOR**

**Office of the Secretary**

**Agency Information Collection**

**Activities: OMB Emergency Approval and Proposed Renewal; Comment Request**

**AGENCY:** Office of the Secretary (OS), Interior.

**ACTION:** Notice of an OMB emergency approval and of extension of an information collection (1093-0004).

**SUMMARY:** To comply with the Paperwork Reduction Act of 1995 (PRA), we are inviting comments on a collection of information that the Office of Management and Budget (OMB) approved on an emergency basis on June 24, 2003, and that we will submit to OMB for review and approval as a continuing information collection. The information collection request (ICR) concerns the paperwork requirements to carry out the Take Pride In America Program Act, 16 U.S.C. 4601-4608.

**DATES:** Submit written comments by September 22, 2003.

**ADDRESSES:** Mail or hand carry comments to the Department of the Interior, Office of the Secretary, Take Pride In America Program, MS-3459, 1849 C Street, NW., Washington, DC 20240. If you wish to e-mail comments, the address is: *TakePride@ios.doi.gov*. Reference "Information Collection 1093-0004" in your e-mail subject line and mark your message for return receipt. Include your name and return address in your message.

**FOR FURTHER INFORMATION CONTACT:** Marti Allbright, Take Pride In America, 202-208-5848. You may also contact Marti Allbright to obtain a copy, at no cost, of the Take Pride In America Program Act that necessitates this collection of information.

**SUPPLEMENTARY INFORMATION:**

*Title:* Take Pride In America National Awards Application/Nomination Process.

*OMB Control Number:* 1093-0004.

*Abstract:* Under the Take Pride In America Program Act (Act), 16 U.S.C. Sec. 4601-4608, the Secretary is to: (1) "conduct a national awards program to honor those individuals and entities which, in the opinion of the Secretary of the Interior \* \* \* have distinguished themselves in activities" under the purposes of the Act; and also to (2) "establish and maintain a public awareness campaign in cooperation with public and private organizations and individuals—(A) to instill in the public the importance of the appropriate use of, and appreciation for Federal, State, and local lands, facilities, and natural and cultural resources; (B) to encourage an attitude of stewardship and responsibility toward these lands, facilities, and resources; and (C) to promote participation by individuals, organizations, and communities of a conservation ethic in caring for these lands, facilities, and resources." The Act states that "[t]he Secretary is authorized \* \* \* generally to do any and all lawful

acts necessary or appropriate to further the purposes of the TPIA Program."

The Take Pride In America (TPIA) Program was re-launched on April 16, 2003. The Program will collect information provided voluntarily by individuals or organizations about their events and activities to further the purposes of the Act in order to select finalists and winners of the annual Take Pride In America National Awards. The TPIA National Awards recognize the valuable and significant contributions that individuals and organizations make in support of stewardship of America's lands. Their tireless and creative efforts play a vital role in protecting, conserving, and enhancing America's wealth of natural, historical, and cultural resources. These awards recognize the efforts of individuals and organizations in both the public and private sectors for outstanding stewardship involving Federal, State, local, Tribal, and private lands.

We will use the information collected primarily to select finalists and winners of the TPIA National Awards. Information also will be used to assure the integrity of the Program (so that, for example, an individual or organization does not receive an award twice for the same project), for reporting on the accomplishments of the Program, for the public awareness campaign (such as press releases and website information on winning projects); and to further the purposes of the Act (such as fostering partnerships and coordination of projects).

OMB approved TPIA's application instructions and form on June 24, 2003, on an emergency basis, with an expiration date of December 31, 2003. The approved application instructions and form can be reviewed through the Internet, on <http://www.TakePride.gov>.

We will process any information in accordance with the Freedom of Information Act (5 U.S.C. 552) and its implementing regulations at the