

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may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this draft guidance.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 The draft guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.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An electronic version of this draft guidance is available on the Internet at 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;