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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier A. Corbin

Mid-Year Stakeholder Meeting on the Implementation of MDUFMA Provisions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of Meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following meeting: Mid-Year Stakeholder Meeting on the Implementation of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA). The topic to be discussed is the agency's progress in implementing the various MDUFMA provisions, including the guidances FDA has issued on the new law.

Date and Time: The meeting will be held on Friday, June 6, 2003, 8:30 a.m. to 12:30 p.m.

Location: The meeting will be held at the Wyndham Washington Hotel, 1400 M St., NW., Washington, DC.

Contact: Cindy I. Garris, Center for Devices and Radiological Health (HFZ-200), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-443-2845, FAX: 301-443-8810, e-mail: CIG@cdrh.fda.gov.

Registration: Send registration information (including name, title, firm name, address, telephone and fax number), and written material and requests to make oral presentations to the contact person by May 23, 2003. If you need special accommodations due to a disability, please contact Cindy Garris, Center for Devices and Radiological Health (HFZ-200), 1350 Piccard Dr., Rockville, MD 20850, 301-443-2845, at least 7 days in advance.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page.

SUPPLEMENTARY INFORMATION:

I. Background Information

On October 26, 2002, MDUFMA amended the Federal Food, Drug, and Cosmetic Act to include several significant new provisions. These provisions authorize: (1) User fees for certain premarket applications, (2) establishment inspections by FDA-accredited persons (third-parties), and (3) new requirements for reprocessed single-use devices (SUDs). In addition, the new law contains several provisions that, while narrower in scope than these provisions, are significant changes to the device law. These include a modular review program for premarket approval applications (PMAs), electronic labeling for certain prescription devices, several provisions concerning devices for pediatric use, and a new labeling requirement that requires the manufacturer's name to appear on the device itself, with certain exceptions.

Over the last several months, the agency has been working to implement the new law. During this time, FDA: (1) Has established a user fee program with payment, billing, and appeals procedures; (2) worked to meet statutory timeframes for the release of the accreditation criteria for persons conducting third party inspections and the identification of certain reprocessed single-use devices that will be subject to additional premarket requirements; (3) published several guidances, such as those related to PMA supplement definitions and

bundling of multiple devices in a single application; and (4) is drafting other documents to be issued in the near future.

II. Agenda

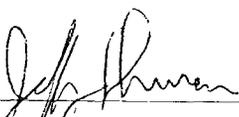
On June 6, 2003, FDA is providing the opportunity for all interested persons to provide information and share their views on the implementation of MDUFMA. At this time, FDA is particularly interested in receiving comments from stakeholders on the payment and billing procedures it has developed as well as on the guidance documents that will be released by the date of the meeting. The agency is also interested in receiving recommendations about other provisions yet to be implemented both in terms of their priority for implementation and specifics on the implementation itself.

Therefore, topics for discussion will include: (1) User fee program for premarket review, e.g., payment and billing procedures, appeals processes, and small business fees; (2) accredited persons; (3) FDA-identified reprocessed single-use devices that will require premarket submission of validation data and the associated guidance; and (4) guidances (either released for comment or under development) to include those that address various PMA issues (supplement definitions, modular review), bundling multiple devices/indications for use in a single application, clinical studies of pediatric devices, electronic labeling for prescription devices intended for use in healthcare facilities, and identification of the manufacturer on the device itself.

FDA will place a copy of any material or comments it receives on MDUFMA implementation on display at the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm 1061, Rockville, MD 20852. Comments are to be identified with the docket number

found in brackets in the heading of this document. Received comments and materials may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 4/25/03
April 25, 2003.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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