

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0422]

2363 103 SEP 25 15 54

DMP Display Date 9-26-03
Publication Date 9-29-03
Certifier R LEDESMA

**Annual Stakeholder Meeting on the Implementation of the Medical Device
User Fee Modernization Act of 2002 Provisions; Public Meeting**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

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

DATES: The meeting will be held on December 3, 2003, from 9 a.m. to 5 p.m. at the Gaithersburg Hilton Hotel, 690 Perry Pkwy., Gaithersburg, MD 20877. Registration is required by November 3, 2003. All individuals wishing to make a presentation or to speak on an issue also must indicate their intent and the topic to be addressed and provide an abstract of the topic to be presented by November 3, 2003. Time for presentations will be limited to 10 minutes.

ADDRESSES: Send written requests to make a 10-minute oral presentation to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Send electronic requests to make a 10-minute oral presentation to <http://www.fda.gov/dockets/ecomments>. Include your name, title, firm name, address, telephone, and fax number with your request. All requests and

presentation materials must include the docket number found in brackets in the heading of this document. Submit all requests and presentation materials by November 3, 2003.

FOR FURTHER INFORMATION CONTACT: Sherrie Appel, 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: *saa@cdrh.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On October 26, 2002, MDUFMA amended the Federal Food, Drug, and Cosmetic Act to include several new significant provisions. MDUFMA authorizes the following provisions: (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. In addition, the new law contains several provisions that, while narrower in scope than the previously mentioned 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.

The agency has been working to implement the new law since its passage in October 2002. During this time, FDA has accomplished the following milestones: Established a user fee program with payment, billing, and appeals procedures; met 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; and published several guidances, such as those related to PMA supplement definitions and bundling of multiple devices in a single application. The agency is drafting other documents to be issued in the near future.

Agenda: On December 3, 2003, FDA is providing the opportunity for all interested persons to provide information and share their views on the implementation of MDUFMA. The agenda will consist of the following panel sessions that will include panelists from FDA, industry, and other stakeholders:

- Panel 1: How is the User Fees Process Working? This panel will consider the small business determinations and the user fee process and performance goals:

- Panel 2: Electronic Labeling and Identification of the Manufacturer on the Device. This panel will address electronic labeling for prescription devices intended for use in healthcare facilities (section 206 of MDUFMA (Public Law 107–250)) and identification of the manufacturer on the device itself (section 301 of MDUFMA (Public Law 107–250)).

- Panel 3: Bundling, Modular PMA, and Expedited PMAs. This panel will discuss guidances that address various PMA issues, including definitions of supplements, modular review, bundling multiple devices/indications for use in a single application, and clinical studies of pediatric devices.

- Panel 4: Third-Party Inspection Program. This panel will discuss implementation of the program, including eligibility criteria for use of a third party by a manufacturer.

- Panel 5: Reuse. This panel will discuss FDA-identified reprocessed single-use devices that will require premarket submission of validation data and the associated guidance for submission of data.

- General Discussion Period From the Floor: At the conclusion of the panels, there will be a general discussion from the floor.

Also at this time, FDA is particularly interested in receiving comments from stakeholders on other topics for discussion. The agency is 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.

FDA will place an additional copy of any material it receives on the docket for this document (2003N-0422). Comments and materials may be seen at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday (see **ADDRESSES**).

Registration: Online registration for the meeting is required by November 3, 2003. Acceptance will be on a first-come, first-served basis. There will be no onsite registration. Please register online at <http://www.fda.gov/cdrh/meetings/120303.html>. FDA is pleased to provide the opportunity for interested persons to listen from a remote location to the live proceedings of the meeting. In order to ensure that a sufficient number of call-in lines are available, please register to listen to the meeting at <http://www.fda.gov/cdrh/meetings/120303.html> by November 3, 2003. Persons without Internet access may register for the onsite meeting or to listen remotely by calling 301-443-2845 by November 3, 2003.

If you need special accommodations due to a disability, please contact Sherrie Appel at 301-443-2845 at least 7 days in advance.

Transcripts: Following the meeting, transcripts will be available for review at the Division of Dockets Management (see **ADDRESSES**).

Dated: 9-22-03
September 22, 2003.

Linda S. Kahan

Linda S. Kahan,
Deputy Director,
Center for Devices and Radiological Health.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

BILLING CODE 4160-01-S

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**

Gregory Jackson