DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Second Annual Stakeholder Meeting on the Implementation of the Medical Device User Fee and 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: Second 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 public meeting will be held on November 18, 2004, from 9 a.m. to 5 p.m. Registration is required by Friday, October 22, 2004. All individuals wishing to make a presentation or to speak on an issue should indicate their intent and the topic to be addressed and provide an abstract of the topic to be presented by October 22, 2004. Time for presentations will be limited to 10 minutes.

ADDRESSES: The public meeting will be held at the Marriott Gaithersburg Washingtonian Center, 9751 Washingtonian Blvd., Gaithersburg, MD.

Submit written requests to make an oral presentation to Cindy Garris, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–6597, ext.

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121, FAX: 301–443–8818, e-mail: *cxg@cdrh.fda.gov*. Include your name, title, firm name, address, telephone, and fax number with your request. All requests and presentation materials should include the docket number found in brackets in the heading of this document. Submit all request for suggestions and recommendations to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Cindy Garris, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–6597, ext. 121, FAX: 301–443–8818, e-mail: *cxg@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 of good manufacturing practice (GMP) 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 significant milestones: (1) Established a user fee program with payment, billing, and appeals procedures; (2) published accreditation criteria for persons conducting third-party inspections and accredited 15 such persons; (3) identified certain reprocessed single-use devices that will be subject to additional marketing requirements; and (4) published guidances related to the PMA, premarket notification (510(k)), and biologics license application (BLA) programs, bundling multiple devices in a single application, and premarket review of pediatric devices. The agency is drafting additional documents to be issued in the near future.

II. Agenda

On November 18, 2004, FDA is providing the opportunity for all interested persons to provide information and share their views on the implementation of MDUFMA. The following topics will be discussed:

• User Fees Process—This panel will consider the small business determination and the user fee payment processes.

Premarket Review Performance Goals—This panel will discuss the agency's progress in meeting the PMA, 510(k), and BLA review performance goals.

• Qualitative Performance Goals (e.g., Modular PMA and GMP and Bioresearch Monitoring (BIMO) Inspection Programs)— This panel will discuss the agency's progress in developing various qualitative performance goals, such as those related to the modular PMA and GMP inspection programs. This panel will also discuss internally-established milestones for the BIMO inspection process.

• Third-Party Inspection Program—This panel will discuss implementing guidances for the program, including establishment eligibility criteria for inspection by a third party.

• Reuse— This panel will discuss the FDA-identified reprocessed single-use devices that require submission of certain validation data and the guidance that describes the agency's review procedures for such submissions. This panel will also report on FDA's progress in reviewing the validation data submissions.

At the conclusion of the meeting, there will be a general discussion from the floor.

III. Registration

Online registration for the meeting is required by October 22, 2004. 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 October 22, 2004. Persons without Internet access may register for the onsite meeting or to listen remotely by calling 301–443–6597, ext. 121 by October 22, 2004.

If you need special accommodations due to a disability, please contact Cindy Garris at 301–443–6597, ext. 121 at least 7 days in advance.

IV. Request for Suggestions, Recommendations, and Materials

FDA is particularly interested in receiving suggestions 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. Send suggestions or recommendations to the Division of Dockets Management (see **ADDRESSES**).

FDA will place an additional copy of any material it receives on the docket for this document (2004N–0423). Suggestions, recommendations, and materials may be seen at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday (see **ADDRESSES**).

V. Transcripts

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

Dated: 9/22/04
September 22, 2004.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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