

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N-0364]

Stakeholder Meeting to Discuss the Possible Implementation of Two Review Performance Goals Referenced in the Medical Device User Fee and Modernization Act of 2002; 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: Stakeholder Meeting to Discuss the Possible Implementation of Two Review Performance Goals referenced in the Medical Device User Fee and Modernization Act of 2002 (MDUFMA). In a letter that accompanied the user fee legislation, the agency committed to a number of review performance goals. These goals include a commitment that 50 percent of the premarket approval applications received in fiscal year (FY) 2007 will have an FDA decision in 180 days and 80 percent of the premarket notifications will have an FDA decision in 90 days. The letter states that these goals are to be re-evaluated following the end of FY 2005 and FDA is to hold a public meeting to consult with its stakeholders and to determine whether the goals are appropriate for implementation in FY 2007.

DATES: The public meeting will be held on May 22, 2006, from 9 a.m. to 12 p.m. However, depending upon the level of public participation, the meeting may end early. Registration is required by May 19, 2006. All individuals wishing to make a presentation on the implementation of these two

performance goals in FY 2007 should indicate their intent and provide an abstract of their presentation by May 10, 2006.

ADDRESSES: The public meeting will be held at the Center for Devices and Radiological Health, 9200 Corporate Blvd., rm. 20B, Rockville, MD 20850.

Submit written requests to make an oral presentation to Cindy Garris (see **FOR FURTHER INFORMATION CONTACT**). 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 requests 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: *cynthia.garris@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On October 26, 2002, MDUFMA amended the Federal Food, Drug, and Cosmetic Act (the act) to authorize user fees for the review of certain premarket applications. In addition, in a letter that accompanied the user fee legislation (goals letter found at: *http://www.fda.gov/cdrh/mdufma/pgoals.html*), the agency committed to a number of review performance goals for premarket applications, including premarket approval applications (PMAs) and premarket notifications (510(k)s) that become more challenging with each FY.

Under the goals letter, 50 percent of the PMAs received in FY 2007 are to have an FDA decision in 180 days and 80 percent of the 510(k)s are to have

an FDA decision in 90 days. The goals letter further states that these goals are to be re-evaluated following the end of FY 2005, and FDA will hold a public meeting to consult with its stakeholders and to determine whether this goal is appropriate for implementation in FY 2007. If FDA determines that the goal is not appropriate, prior to August 1, 2006, the Secretary of Health and Human Services will send a letter to the Committee on Health, Education, Labor, and Pensions of the Senate and to the Energy and Commerce Committee, Subcommittee on Health of the House of Representatives, stating that the goal will not be implemented and the rationale for its removal.

Since its passage in October 2002, the agency has been working to implement MDUFMA. An important part of this process has been the annual stakeholder meetings, during which interested persons have been afforded the opportunity to share information and views on the implementation of MDUFMA. FDA is continuing this outreach to its stakeholders by holding this public meeting. During this meeting, FDA encourages stakeholders to provide their input and recommendations on the implementation of these two performance goals in FY 2007.

For additional information on MDUFMA, please see the document entitled “Background on MDUFMA” at <http://www.fda.gov/cdrh/mdufma/whitepaper.html>.

II. Agenda

On May 22, 2006, FDA is providing the opportunity for interested persons to share their views on the implementation of the FY 2007 PMA and 510(k) performance goals discussed previously in this document. FDA stakeholders may offer their input and recommendations on these two performance goals.

III. Registration

Online registration for the meeting is required by May 19, 2006. 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/052206.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/052206.html> by May 19, 2006. Persons without Internet access may register for the onsite meeting or to listen remotely by calling 301-443-6597, ext. 121 by May 19, 2006.

If you need special accommodations due to a disability, please contact Cindy Garris at least 7 days in advance of the meeting.

IV. Request for Input and Materials

FDA is also interested in receiving input from stakeholders on other issues related to future user fee legislation. 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 (2005N-0364). Suggestions, recommendations, and materials may be seen at the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

V. Transcripts

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

Dated: April 6, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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