Public Workshop - Medical Device User Fee Program Public Meeting, March 28, 2012

U.S. Food & Drug Administration

The purpose of the meeting is to provide an opportunity for stakeholders to present their views on the draft recommendations for the reauthorization of the medical device user fee program. We welcome this opportunity to hear from stakeholders as we conclude negotiations for the next reauthorization of the medical device user fee program.

Date, Time and Location

FDA is planning to hold this meeting on March 28, 2012. Registration will begin at 8:00am and the meeting will begin promptly at 9:00am at the following location:

Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

- Directions and Metro Information [9]

The meeting will also be webcast. Registration is required to view the webcast.

Background

The Food and Drug Administration (FDA) is announcing their intent to hold a public meeting to discuss proposed recommendations for the reauthorization of the Medical Device User Fee Act (MDUFA) for fiscal years (FYs) 2013 through 2017. MDUFA authorizes FDA to collect user fees and use those fees for the process for the review of device applications. The current legislative authority for MDUFA expires on October 1, 2012. New legislation will be required for FDA to collect medical device user fees for future fiscal years.

As required by Section 738A(b)(2), (3), and (6) of the FD&C Act (21 U.S.C. 379j-1(b)(2), (3), and (6)), FDA obtained prior public input and negotiated an agreement with regulated industry while periodically consulting with patient and consumer advocacy groups and made minutes of negotiation and stakeholder meetings publicly available [10]. Section 738A(b)(4) of the FD&C Act (21 U.S.C. 379j-1(b)(4)), requires that, after holding negotiations with regulated industry and before transmitting the Agency's final recommendations to Congress for the reauthorized program (MDUFA III), FDA do the following: (1) present the draft recommendations to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate, (2) publish the draft recommendations in the **Federal Register**, (3) providea period of 30 days for the public to provide written comments on the draft recommendations, (4) hold a meeting at which the public may present its views on the draft recommendations, and (5) after consideration of public views and comments, revise the draft recommendations as necessary.

FDA and regulated Industry have completed negotiations; FDA now invites public comment on the draft recommendations for the next reauthorized program. After the public meeting and the public comment period, FDA will revise the draft recommendations as necessary. In addition, the Agency will present the draft recommendations to the Congressional committees.

The purpose of the upcoming meeting is to hear stakeholder views on the draft recommendations for the reauthorized program (MDUFA III). The following information is provided to help potential meeting participants better understand the history and evolution of the medical device user fee program and the current status of the MDUFA III draft recommendations.

Proposed Recommendations

The proposed recommendations for MDUFA III address many of the priorities and concerns identified by public stakeholders and the device industry, and many of the important challenges identified by FDA. Each recommendation is briefly described in the Federal Register notice with reference to the section of the draft commitment letter where more detailed information can be found. Further description of the proposed goals and commitments can be found in the draft MDUFA III commitment letter.

In conjunction with the proposed enhancements and performance goals outlined in the draft commitment letter, FDA is proposing new user fees and several statutory changes. The specific proposals are briefly described in the Federal Register notice. Further description of the proposed fee structure and proposed statutory changes can be found in the draft MDUFA III legislative language.

- Draft MDUFA III Commitment Letter [11]
- Draft MDUFA III Legislative Language [12]

Draft Agenda

Time	Subject	Name of Speaker
8:00 am	Registration	
9:00 am	Welcome	TBD *Moderator*
9:05 am	Opening Remarks	Stephen Spielberg, MD, PhD, Deputy Commissioner for Medical Products and Tobacco, FDA Jeffrey Shuren, MD, JD, Director, Center for Devices and Radiological Health, FDA Karen Midthun, MD, Director, Center for Biologics Evaluation and Research, FDA
9:30 am	FDA Perspective	Malcolm Bertoni, Assistant Commissioner for Planning, FDA
10:15 am	Break	
10:30 am	Stakeholder Perspectives – Panel 1	TBD
11:15 am	Stakeholder Perspectives – Panel 2	TBD
12:00 pm	Lunch Break	
1:00 pm	Stakeholder Perspectives – Panel 3	TBD
1:45 pm	Regulated Industry Perspectives	TBD
2:30 pm	Open Comment Period	
3:45 pm	Closing Remarks	Malcolm Bertoni, Assistant Commissioner for Planning, FDA

Transcripts

Transcripts will be posted approximately two weeks after the Public Meeting.

Public Comment

Any person may submit written or electronic comments to the Division of Dockets

Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 http://www.regulations.gov [13]. It is only necessary to send one set of comments. Comments are to be identified with the docket number [Docket No. FDA-2010-N-0389]. Received comments may be seen in the Division of Dockets Management between 9am and 4pm, Monday through Friday.

Registration to Attend the Meeting

If you wish to attend this meeting or view by webcast, you must register by close of business on March 26, 2012.

There is no fee to register for the meeting and registration will be on a first-come, first-served basis. Early registration is recommended because seating is limited.

If you wish to make an oral presentation during any of the open comment sessions at the meeting you must indicate this at the time of registration. FDA requests that presentations focus on the areas defined in the Federal Register Notice. You should also identify which discussion topic you wish to address in your presentation and you must submit a brief statement that describes your experience and/or expertise relevant to your proposed presentation. In order to keep each open session focused on the discussion topic at hand, each oral presentation should address only one discussion topic. FDA will do its best to accommodate requests to speak.

Attendance	❍ In-Person ❍ Webcast
Title	❍ Mr. ❍ Mrs. ❍ Ms. ❍ None
First Name *	
Last Name *	M.D.❑ Ph.D.❑
Email *	
	Please enter Email again for verification :
Phone Number*	(No dashes or spaces in phone numbers please)
Company or Organization *	
Request to Speak	To request to speak during the open public comment session, please supply the topic you wish to address:

Submit Clear Form

Contact Us

If you require special accommodations due to a disability, or need additional information regarding registration, please contact Cindy Garris, Office of Communications, Education, and Radiation Programs, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 66, Silver Spring, MD 20993, 301-796-5861, FAX: 301-847-8142, MDUFAReauthorization@fda.hhs.gov [14].

For questions regarding meeting content please contact Cindy Garris, Office of Communications, Education, and Radiation Programs, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 66, Silver Spring, MD 20993, 301-796-5861, FAX: 301-847-8142, MDUFAReauthorization@fda.hhs.gov [14]

SOURCE [15]

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