

Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892-9529, 301-435-6033, rajarams@mail.nih.gov. (Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: August 9, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-20019 Filed 8-12-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Microbiology, Infectious Diseases and AIDS Initial Review Group; Microbiology and Infectious Diseases Research Committee.

Date: October 14, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Courtyard by Marriott, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Michelle M. Timmerman, PhD, Scientific Review Officer, Scientific Review Program, DEA/NIAID/NIH/DHHS, Room 2217, 6700B Rockledge Drive, MSC-7616, Bethesda, MD 20892-7616, 301-451-4573, timmermanm@niaid.nih.gov. (Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: August 9, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-20015 Filed 8-12-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Fogarty International Center; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Fogarty International Center Advisory Board.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in section 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the Discussions could disclose confidential trade secrets or commercial property such as patentable materials, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Fogarty International Center Advisory Board.

Date: September 14, 2010.

Closed: 8 a.m. to 9:30 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Lawton Chiles International House, Bethesda, MD 20892.

Open: 9:30 a.m. to 3 p.m.

Agenda: A report of the FIC Director on updates of current and planned FIC activities. Topics to be discussed: Communications Strategy; and Global Research Priorities in Maternal, Newborn, and Child Health.

Place: National Institutes of Health, Lawton Chiles International House, Bethesda, MD 20892.

Contact Person: Robert Eiss, Public Health Advisor, Fogarty International Center, National Institutes of Health, 31 Center Drive, Room B2C02, Bethesda, MD 20892, (301) 496-1415, EISSR@MAIL.NIH.GOV.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one

form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit. Information is also available on the Institute's/Center's home page: <http://www.nih.gov/fic/about/advisory.html>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: August 9, 2010.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-20012 Filed 8-12-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2010-N-0389]

Medical Device User Fee Act; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting on the reauthorization of the medical device user fee program. The current legislative authority for the medical device user fee program expires in September 2012 and new legislation will be required for FDA to continue collecting user fees for the medical device program. The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that before FDA begins negotiations with the regulated industry on medical device user fee program reauthorization, we publish a notice in the **Federal Register** requesting public input on the reauthorization, hold a public meeting at which the public may present its views on the reauthorization, provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes, and publish the comments on FDA's Web site. FDA invites public comment on the medical device user fee program and suggestions regarding the commitments FDA should propose for the next reauthorized program.

Date and Time: The public meeting will be held on September 14, 2010, from 9 a.m. to 5 p.m.

Location: FDA is currently in the process of determining the meeting location, which will be in the Washington DC metropolitan area. When the location has been determined, FDA plans to publish a notice in the **Federal Register** that will provide the address of the meeting location.

Contact Person: James Swink, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1609, Silver Spring, MD 20993, 301-796-6313, FAX: 301-847-8121, James.Swink@fda.hhs.gov.

Registration and Requests for Oral Presentations: If you wish to attend and/or present at the meeting, please register by August 31, 2010. Please register at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm218250.htm>. Those without e-mail access may register by contacting James Swink (see *Contact Person*). Please provide complete contact information for each attendee, including name, title, firm name, address, e-mail address, telephone and fax number. Registrants wishing to make a presentation or provide public comments should note that when registering. Registration is free and will be on a first-come, first-served basis. Early registration is recommended because seating is limited. FDA may limit the number of participants from each organization, as well as the total number of participants, based on space limitations to ensure representation of all stakeholder interest groups. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability. We will try to accommodate all persons who wish to make a presentation or public comments. The time allotted for presentations may depend on the number of persons who wish to speak.

If you need special accommodations due to a disability, please contact James Swink at least 7 days in advance.

Comments: Regardless of attendance at the public meeting, interested persons may submit either electronic or written comments by October 14, 2010. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number

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

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing its intention to hold a public meeting on the reauthorization of the medical device user fee program. The authority for such program expires in September 2012. Without new legislation, user fees can no longer be collected by FDA to fund the medical device review process. Section 738A(b)(2) of the FD&C Act (21 U.S.C. 379j-1(b)(2)) requires that, before FDA begins negotiations with the regulated industry on user fee reauthorization, we do the following: (1) Publish a notice in the **Federal Register** requesting public input on the reauthorization; (2) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in section 738A(a)(1); (3) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this part; and (4) publish the comments on the Food and Drug Administration's Web site. This notice, the public meeting, the 30 day comment period after the meeting, and the posting of the comments on the FDA Web site will satisfy these requirements. The purpose of the meeting is to hear stakeholder views on medical device user fee reauthorization as we consider the features to propose in the next medical device user fee program. FDA is interested in responses to the following two general questions and welcomes any other pertinent information stakeholders would like to share:

1. What is your assessment of the overall performance of the medical device user fee program thus far?
2. What aspects of the medical device user fee program should be retained, changed, or discontinued to further strengthen and improve the program?

The following information is provided to help potential meeting participants better understand the history and evolution of the medical device user fee program and its current status.

II. What is the Medical Device User Fee Program? What Does It Do?

In the years preceding enactment of Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250), FDA's medical device program suffered a long-term, significant loss of resources that

undermined the program's capacity and performance. MDUFMA was enacted "in order to provide the Food and Drug Administration (FDA) with the resources necessary to better review medical devices, to enact needed regulatory reforms so that medical device manufacturers can bring their safe and effective devices to the American people at an earlier time, and to ensure that reprocessed medical devices are as safe and effective as original devices."¹ MDUFMA had a 5-year life and contained two particularly important features which relate to reauthorization:

- *User fees* for the review of medical device premarket applications, reports, supplements, and premarket notification submissions provided additional resources to make FDA reviews more timely, predictable, and transparent to applicants. MDUFMA fees and mandated appropriations for the medical device program helped FDA expand available expertise, modernized its information management systems, provided new review options, and provided more guidance to prospective applicants. The ultimate goal was to approve and clear safe and effective medical devices more rapidly, benefiting applicants, the health care community, and most importantly, patients.

- *Negotiated performance goals* for many types of premarket reviews provided FDA with benchmarks for measuring review improvements. These quantifiable goals became more demanding each year and include FDA decision goals and cycle goals (cycle goals refer to FDA actions prior to a final action on a submission). Under MDUFMA, FDA must also have met several other commitments that do not have specific timeframes or direct measures of performance, such as expanding the use of meetings with industry, maintenance of current performance in review areas where specific performance goals have not been identified, and publication of additional guidance documents.

Medical device user fees and increased appropriations were viewed by FDA, Congress, and industry stakeholders as essential to support high-quality, timely medical device reviews, and other activities critical to the device review program.

MDUFMA provided for fee discounts and waivers for small businesses. Small businesses make up a large proportion of the medical device industry, and these discounts and waivers helped reduce the financial impact of the user

¹ H.R. Rep. No. 107-728, at 21 (2002).

fees on this sector of the device industry, which plays an important role in fostering innovation.

The negotiated performance goals and commitments that do not have specific timeframes or direct measures of performance set under MDUFMA were comprehensive and demanding. By Fiscal Year (FY) 2007, approximately 85 performance goals and commitments were in effect. FDA provided periodic reports on its progress towards meeting these performance goals and commitments to its stakeholders and Congress. FDA also provided an annual financial report to Congress that helped to ensure transparency and accountability of its use of the additional resources provided by MDUFMA.

In 2007, Congress reauthorized medical device user fees through FY 2012 under the Medical Device User Fee Amendments of 2007 (MDUFA) (title II of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110–85)).

Under MDUFA, the user fee program remained intact, with a few significant modifications to the program. The user fee framework was changed to provide a more reliable and stable funding stream. Specifically, MDUFA included establishment registration as a new fee type that provided a more predictable amount of funds that could be collected by the Agency in any given year. MDUFA also saw changes to the performance goals. Compared to MDUFMA, there were fewer performance goals under MDUFA, yet the goals were more demanding. Specifically, individual cycle goals were removed and tighter overall goals were implemented. This was done to facilitate a more interactive review process. Specific timelines were established under MDUFA for Modular Premarket Approvals (PMAs) and Real-Time PMA supplements, which were not included under MDUFMA in 2002. The commitment letter outlining the goals in the last reauthorization can be found at <http://www.fda.gov/MDUFA>. FDA published a number of reports that provide the public with useful background on MDUFMA, FDAAA, and MDUFA. Key **Federal Register** documents, MDUFA-related guidance documents, legislation, performance reports, and financial reports and plans can be found at <http://www.fda.gov/MDUFA>. FDA will also post a webinar on the medical device user fee program to give the public more background information on the program. The webinar will be available through the link to the Public Meeting at <http://www.fda.gov/MedicalDevices/>

NewsEvents/WorkshopsConferences/ucm218250.htm approximately 10 days before the public meeting. FDAAA specific information is available at <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCAAct/SignificantAmendmentstotheFDCAAct/FoodandDrugAdministrationAmendmentsActof2007/default.htm>.

III. What Information Should You Know About the Meeting?

A. When and Where Will the Meeting Occur? What Format Will FDA Use?

Through this notice, we are announcing a public meeting to hear stakeholder views on the reauthorization of the medical device user fee program, including specific suggestions for any changes to the program that we should consider. We will conduct the meeting on September 14, 2010. In general, the meeting format will include presentations by FDA and a series of panels representing different stakeholder interest groups (such as patient advocates, consumer protection, industry, health professionals, and academic researchers). We will also provide an opportunity for individuals to make presentations at the meeting and for organizations and individuals to submit written comments to the docket after the meeting. FDA policy issues are beyond the scope of these reauthorization discussions. Accordingly, the presentations should focus on program improvements and funding issues, including specific suggestions for changes to performance goals, and not focus on policy issues.

B. What Questions Would FDA Like the Public to Consider?

Please consider the following questions for this meeting:

1. What is your assessment of the overall performance of the medical device user fee program thus far?
2. What aspects of the medical device user fee program should be retained, changed, or discontinued to further strengthen and improve the program?

C. Will Meeting Transcripts be Available?

Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be available in either hard copy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of

Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857.

Dated: August 6, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–19843 Filed 8–12–10; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2009–0097]

Notice of Availability of Final Environmental Impact Statement for the Goethals Bridge Replacement Project

AGENCY: Coast Guard, DHS.

ACTION: Notice of availability.

SUMMARY: The Coast Guard announces the availability of the Final Environmental Impact Statement for the proposed replacement by the Port Authority of New York and New Jersey of the 82-year old Goethals Bridge across the Arthur Kill between Staten Island, NY, and Elizabeth, NJ. The FEIS analyzes the potential for impact to the natural, human and cultural environment of the proposed Goethals Bridge Replacement Project.

DATES: The review period for the FEIS will close on September 13, 2010. Comments and related material must either be submitted to our online docket via <http://www.regulations.gov> on or before September 13, 2010 or reach the Docket Management Facility by that date.

ADDRESSES: You may submit comments identified by docket number USCG–2009–0097 using any one of the following methods:

- (1) *Federal eRulemaking Portal:* <http://www.regulations.gov>.
- (2) *Fax:* 202–493–2251.
- (3) *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590–0001.

(4) *Hand Delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

To avoid duplication, please use only one of these four methods. See the “Public Participation and Request for Comments” portion of the