

#### IV. FDF Facility Fee

Under GDUFA, the annual FDF facility fee is owed by each person that owns a facility which is identified or intended to be identified, in at least one generic drug submission that is pending or approved, to produce one or more finished dosage forms of the human generic drug. These fees are due no later than 45 days after the publication of this notice. Section 744B(b)(2)(C) of the FD&C Act specifies that the FDF facility fee revenue will make up 56 percent of the remaining \$249,000,000, which is \$139,440,000.

In order to calculate the FDF fee, FDA has used the data submitted by generic drug facilities through the self-identification process mandated in the GDUFA statute and specified in a Notice of Requirement published on October 2, 2012. The total number of FDF facilities identified through self-identification was 758. Of the total facilities identified as FDF, there were 325 domestic facilities and 433 foreign facilities. The foreign facility differential is \$15,000. In order to calculate the fee for domestic facilities, we must first subtract the fee revenue that will result from the foreign facility fee differential. We take the foreign facility differential (\$15,000) and multiply it by the number of foreign facilities (433) to determine the total fees that will result from the foreign facility differential. As a result of that calculation the foreign fee differential will make up \$6,495,000 of the total FDF fee revenue. Subtracting the foreign facility differential fee revenue (\$6,495,000) from the total FDF facility target revenue (\$139,440,000) results in a remaining fee revenue balance of \$132,945,000. To determine the domestic FDF facility fee, we divide the \$132,945,000 by the total number of facilities (758) which gives us a domestic FDF facility fee of \$175,389. The foreign FDF facility fee is \$15,000 more than the domestic FDF facility fee, or \$190,389.

#### V. API Facility Fee

Under GDUFA, the annual API facility fee is owed by each person that owns a facility which produces, or which is pending review to produce, one or more active pharmaceutical ingredients identified, or intended to be identified, in at least one generic drug submission that is pending or approved or in a Type II active pharmaceutical ingredient drug master file referenced in such generic drug submission. These fees are due no later than 45 days after the publication of this notice. Section 744B(b)(2)(D) of the FD&C Act specifies that the API facility fee will make up 14

percent of the remaining \$249,000,000 fee revenue, which is \$34,860,000.

In order to calculate the API fee, FDA has used the data submitted by generic drug facilities through the self-identification process. Of the total facilities identified as API, there were 122 domestic facilities and 763 foreign facilities. The foreign facility differential is \$15,000. In order to calculate the fee for domestic facilities, we must first subtract the fee revenue that will result from the foreign facility fee differential. We take the foreign facility differential (\$15,000) and multiply it by the number of foreign facilities (763) to determine the total fees that will result from the foreign facility differential. As a result of that calculation the foreign fee differential will make up \$11,445,000 of the total API fee revenue. Subtracting the foreign facility differential fee revenue (\$11,445,000) from the total API facility target revenue (\$34,860,000) results in a remaining balance of \$23,415,000. To determine the domestic API facility fee, we divide the \$23,415,000 by the total number of facilities (885) which gives us a domestic API facility fee of \$26,458. The foreign API facility fee is \$15,000 more than the domestic API facility fee, or \$41,458.

#### VI. Fee Payment Options and Procedures

To make a payment of the facility fee, you must complete a Generic Drug User Fee Cover Sheet, available on the FDA Web site (<http://www.fda.gov/gdufa>) and generate a user fee payment identification (ID) number. Payment must be made in U.S. currency drawn on a U.S. bank by electronic check, check, bank draft, U.S. postal money order, or wire transfer.

FDA has partnered with the U.S. Department of the Treasury to utilize Pay.gov, a Web-based payment application, for online electronic payment. The Pay.gov feature is available on the FDA Web site after completing the Generic Drug User Fee Cover Sheet, and generating the user fee payment ID number.

Please include the user fee payment ID number on your check, bank draft, or postal money order, and make payable to the order of the Food and Drug Administration. Your payment can be mailed to: Food and Drug Administration, P.O. Box 979108, St. Louis, MO 63197-9000. If checks are to be sent by a courier that requests a street address, the courier can deliver the checks to: U.S. Bank, Attention: Government Lockbox 979108, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This U.S. Bank address is for

courier delivery only.) Please make sure that the FDA post office box number (P.O. Box 979108) is written on the check, bank draft, or postal money order.

If paying by wire transfer, please reference the user fee payment ID number when completing your transfer. The originating financial institution may charge a wire transfer fee. Please ask your financial institution about the wire transfer fee and include it with your payment to ensure that your facility fee is fully paid. The account information is as follows: New York Federal Reserve Bank, U.S. Department of Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, account number: 75060099, routing number: 021030004, SWIFT: FRNYUS33, Beneficiary: FDA, 1350 Piccard Dr., Rockville, MD, 20850. The tax identification number of the Food and Drug Administration is 53-0196965.

Dated: January 11, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013-00851 Filed 1-16-13; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of Closed Meetings

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 meetings.

The meetings 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:* National Cancer Institute Special Emphasis Panel; NCI Program Project Meeting II.

*Date:* February 4-5, 2013.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

*Contact Person:* Majed M. Hamawy, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH,

6116 Executive Boulevard, Room 8135, Bethesda, MD 20892-8328, 301-594-5659 [mh101v@nih.gov](mailto:mh101v@nih.gov).

*Name of Committee:* National Cancer Institute Special Emphasis Panel; NCI Program Project Meeting I.

*Date:* February 11-12, 2013.

*Time:* 3:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

*Contact Person:* Caterina Bianco, MD, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Boulevard, Room 8134, Bethesda, MD 20892-8328, 301-496-7011 [biancoc@mail.nih.gov](mailto:biancoc@mail.nih.gov).

*Name of Committee:* National Cancer Institute Special Emphasis Panel; NCI Program Project Meeting IV.

*Date:* February 28, 2013.

*Time:* 8:00 a.m. to 8:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Crystal City Marriott at Reagan National Airport, Salon D, 1999 Jefferson Davis Highway, Arlington, VA 22202.

*Contact Person:* Delia Tang, MD, Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH 6116 Executive Boulevard, Room 8123, Bethesda, MD 20892-8328, 301-496-2330, [tangd@mail.nih.gov](mailto:tangd@mail.nih.gov).

*Name of Committee:* National Cancer Institute Special Emphasis Panel; NCI OmniBus Review Meeting.

*Date:* March 11-12, 2013.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

*Contact Person:* Shakeel Ahmad, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Boulevard, Room 8139, Bethesda, MD 20892-8328, (301) 594-0114, [ahmads@mail.nih.gov](mailto:ahmads@mail.nih.gov).

*Name of Committee:* National Cancer Institute Special Emphasis Panel; Early-Stage Innovative Technology Development for Cancer Research (R21)

*Date:* March 20-21, 2013.

*Time:* 8:00 a.m. to 12:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

*Contact Person:* Jeffrey E. DeClue, Ph.D., Scientific Review Officer, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Boulevard, Room 8059, Bethesda, MD 20892-8329, 301-496-7904 [decluej@mail.nih.gov](mailto:decluej@mail.nih.gov).

*Name of Committee:* National Cancer Institute Special Emphasis Panel; Cancer Etiology/Genetics and Prevention.

*Date:* March 28-29, 2013.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

*Contact Person:* Thomas A. Winters, Ph.D., Scientific Review Officer, Special Review & Logistics Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Boulevard, Room 8146, Bethesda, MD 20892-8329, 301-594-1566, [twinters@mail.nih.gov](mailto:twinters@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: January 11, 2013.

**Melanie J. Gray,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; 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:* Center for Scientific Review Special Emphasis Panel, AIDS and Related Research.

*Date:* January 18, 2013.

*Time:* 2:00 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Robert Freund, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5216, MSC 7852, Bethesda, MD 20892, 301-435-1050, [freundr@csr.nih.gov](mailto:freundr@csr.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 11, 2013.

**Anna Snouffer,**

*Deputy Director, Office of Federal Advisory Committee Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; 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:* Center for Scientific Review Special Emphasis Panel; Member Conflict: AIDS and Related Research.

*Date:* January 22, 2013.

*Time:* 11:00 a.m. to 1:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Robert Freund, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5216, MSC 7852, Bethesda, MD 20892, 301-435-1050, [freundr@csr.nih.gov](mailto:freundr@csr.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)