a form that can help them make the most of their benefits and options

The activities under this clearance involve social marketing and consumer research using samples of self-selected customers, as well as convenience samples, and quota samples, with respondents selected either to cover a broad range of customers or to include specific characteristics related to certain products or services. All collection of information under this clearance will utilize a subset of items drawn from a core collection of customizable items referred to as the Social Marketing and Consumer Testing Item Bank. This item bank is designed to establish a set of pre-approved generic question that can be drawn upon to allow for the rapid turn-around consumer testing required for CMS to communicate more effectively with its audiences. The questions in the item bank are divided into two major categories. One set focuses on characteristics of individuals and is intended primarily for participant screening and for use in structured quantitative on-line or telephone surveys. The other set is less structured and is designed for use in qualitative one-on-one and small group discussions or collecting information related to subjective impressions of test materials. A Study Initiation Request Form detailing each specific study (description, methodology, estimated burden) conducted under this clearance will be submitted before any testing is initialed. Results will be compiled and disseminated so that future communication can be informed by the testing results. We will use the findings to create the greatest possible public benefit. *Form Number:* CMS–10437 (OCN: 0938–New); *Frequency:* Yearly; *Affected Public:* Individuals. *Number of Respondents:* 41,592. *Number of Responses:* 28,800. *Total Annual Hours:* 21,488. (For policy questions regarding this collection contact Chris Koepke at 410–786–5877. For all other issues call 410–786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by March 18, 2013:

1. *Electronically.* You may submit your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number ___, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: January 11, 2013.

**Martique Jones,**

*Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2013–00860 Filed 1–16–13; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2013–N–0007]**

### Generic Drug User Fee—Active Pharmaceutical Ingredient and Finished Dosage Form Facility Fee Rates for Fiscal Year 2013

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the rate for the generic drug active pharmaceutical ingredient (API) and finished dosage form (FDF) facilities user fees for fiscal year (FY) 2013. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Generic Drug User Fee Amendments of 2012 (GDUFA), enacted the Food and Drug Administration Safety and Innovation Act, as further amended by the FDA User Fee Corrections Act of 2012, authorizes FDA to assess and collect user fees for certain applications and supplements associated with human generic drug products, on applications in the backlog as of October 1, 2012, on finished dosage form (FDF) and active pharmaceutical ingredient (API) facilities, and on Type II API drug master files (DMF) to be made available for reference. GDUFA directs FDA to establish each year the generic drug user fee rates for the upcoming year. In the first year of GDUFA (FY 2013), some rates will be published in separate **Federal Register** notices because of the timing specified in the statute. Each year thereafter the GDUFA fee rates will be published 60 days before the start of the fiscal year. This document establishes the FY 2013 rate for API and FDF facility fees. These fees are due on March 4, 2013.

**FOR FURTHER INFORMATION CONTACT:** David Miller, Office of Financial Management (HFA–100), Food and Drug Administration, 1350 Piccard Dr., PI50, Rm. 210J, Rockville, MD 20850, 301–796–7103.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

Sections 744A and 744B of the FD&C Act, as added by GDUFA (21 U.S.C. 379j–41 and 379j–42), establish user fees associated with human generic drug products. Fees are assessed on: (1) Certain applications in the backlog as of October 1, 2012; (2) certain types of applications and supplements associated with human generic drug products; (3) certain facilities where human generic drug APIs and FDFs are produced; and (4) certain Type II API DMFs associated with human generic drug products. This notice focuses on the API and FDF facility fees.

#### II. Fee Revenue Amount for FY 2013

The total fee revenue amount for FY 2013 is $299,000,000, as set in the statute. GDUFA directs FDA to use the yearly revenue amount as a starting point to set the fees. GDUFA states that the backlog fee will make up $50,000,000 of the total revenue collected for FY 2013. Therefore, the rest of the fees will make up a percentage of the remaining $249,000,000 of the total fee revenue. For more information about GDUFA, please refer to the FDA Web site (*http://www.fda.gov/gdufa*). The API and FDF facility fee calculations for FY 2013 are described in this document.

#### III. Foreign Differential

Under GDUFA, the fee for a facility located outside the United States and its territories and possessions shall be not less than $15,000 and not more than $30,000 higher than the amount of the fee for a facility located in the United States and its territories and possessions, as determined by the Secretary. The basis for this differential is the extra cost incurred by conducting an inspection outside the United States and its territories and possessions. For FY 2013 FDA has determined that the differential for foreign facilities will be $15,000. The differential may be adjusted in future years.

**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,