4160-01-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:

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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.

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