4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0007]

Generic Drug User Fee--Backlog Fee Rate 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 backlog fee related to generic drug 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), 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 (DMFs) 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 FY. This document establishes the FY 2013 rate for the backlog fee ($17,434). This fee is effective on October 1, 2012.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

Sections 744A and744B of the FD&C Act (21 U.S.C. 379j-41 and 379j-42), as added by GDUFA (Title III of the Food and Drug Administration Safety and Innovation Act (Public Law 112-144), which was signed by the President on July 9, 2012), establish user fees associated with human generic drug products. Fees are assessed on the following: (1) 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 APIs and FDFs are produced; (4) certain type II API DMFs associated with human generic drug products. This notice focuses solely on the backlog fee.

II. Fee Revenue Amount for FY 2013

The total fee revenue amount for FY 2013 is $299,000,000, as set in the statute (section 744B(b)(1)(A) of the FD&C Act). Under that provision, FDA uses the yearly revenue amount as a starting point to set the fees. The GDUFA statute states that the backlog fee will make up $50,000,000 of the total revenue collected for FY 2013 (section 744B(b)(1)(A)(i) of the FD&C Act). For more information about GDUFA, please refer to the FDA Web site (http://www.fda.gov/gdufa). The backlog fee calculation for FY 2013 is described in this document.

III. Backlog Fee

Under GDUFA, each person that owns an abbreviated new drug application that is pending on October 1, 2012, and that has not received a tentative approval prior to that date, shall be subject to a backlog fee for each such application (section 744B(a)(1)(A) of the FD&C Act). The backlog fee is due no later than 30 days after publication of this notice (section 744B(a)(1)(D) of the FD&C Act). The backlog fee is assessed one time only, for FY 2013, and no backlog fee will be assessed in subsequent years. Once incurred, the backlog fee obligation can only be discharged by payment in full.

Under section 744B(a)(1)(B) of the FD&C Act, FDA calculates the backlog fee by taking the exact number of pending abbreviated new drug applications in the backlog that have not received tentative approval as of October 1, 2012, and dividing $50,000,000 by that number. Since there are 2,868 applicable applications in the backlog, the backlog fee is calculated to be $17,434 ($50,000,000 divided by 2,868 rounded to the nearest dollar).

IV. Fee Payment Options and Procedures

To make a payment of the backlog 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 backlog 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: October 16, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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