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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Generic Drug User Fee--Abbreviated New Drug Application, Prior Approval Supplement, and Drug Master File 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 abbreviated new drug application (ANDA), prior approval supplement (PAS), and drug master file (DMF) fees related to the Generic Drug User Fee Program 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), as further amended by the FDA User Fee Correction Act of 2012, authorizes FDA to assess and collect user fees for certain applications and supplements for 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 active pharmaceutical ingredient 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 FY 2013 rates for an ANDA ($51,520), PAS ($25,760), and DMF ($21,340). These fees are effective on October 1, 2012, and will remain in effect through September 30, 2013.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

Sections 744A and 744B 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), as further amended by the FDA User Fee Correction Act of 2012 (Public Law 112-193) (signed by the President on October 5, 2012), establish fees associated with human generic drug products. Fees are assessed on the following: (1) Certain applications in the backlog as of October 1, 2012; (2) certain types of applications and supplements for human generic drug products; (3) certain facilities where APIs and FDFs are produced; and (4) certain DMFs associated with human generic drug products (section 744B(a) of the FD&C Act). This notice will focus on the ANDA, PAS, and DMF 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 fee rates for each fee type. 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 revenue. For more information about GDUFA, please refer to the FDA Web site (http://www.fda.gov/gdufa). The ANDA, PAS, and DMF fee calculations for FY 2013 are described in this document.

III. ANDA and PAS Fees

Under GDUFA, the ANDA and PAS fees are owed by each applicant that submits, on or after October 1, 2012, an ANDA or a PAS. These fees are due on the date of submission of the ANDA or PAS or 30 days after the publication date of this notice, whichever is later. Section 744B(b)(2)(B) specifies that the ANDA and PAS fees will make up 24 percent of the $249,000,000, which is $59,760,000.

In order to calculate the ANDA fee, FDA needed to estimate the number of full application equivalents (FAEs) that will be submitted in FY 2013. Over the past 4 years, the average number of ANDAs that would have been subject to the fee was approximately 850. Because the number of prior approval supplements submitted in FY 2012 is significantly lower than the number submitted in the 2 previous years, FDA has utilized available data concerning FY 2012 to estimate the number of such supplements for FY 2013. The estimated number of PASs to be received in FY 2013 is 576 based on an annualized estimate of the number of receipts for FY 2012.

In estimating the number of fee-paying FAEs, applications count as one FAE and supplements count as one-half an FAE, since the fee for a PAS is one-half of the fee for an ANDA. GDUFA requires that 75 percent of the fees paid for an ANDA or PAS be refunded if its receipt is refused due to issues other than failure to pay fees (section 744B(a)(3)(D) of the FD&C Act). Therefore, an application or supplement that is considered not to have been received by the Secretary due to reasons other than failure to pay fees counts as one-fourth of an

FAE if the applicant initially paid a full application fee, or one-eighth of an FAE if the applicant initially paid the supplement fee (one-half of the full application fee amount).

Taking into account estimates of the number of ANDAs and PASs that are likely to be refused due to issues other than failure to pay fees, and the number that are likely to be resubmitted in the same fiscal year, FDA estimates that the total number of fee-paying FAEs that will be received in FY 2013 is 1,160.

The FY 2013 application fee is estimated by dividing the number of full application equivalents that will pay the fee in FY 2013 (1,160) into the fee revenue amount to be derived from application fees in FY 2013 ($59,760,000). The result, rounded to the nearest $10, is a fee of $51,520 per ANDA. Section 744B(b)(2)(B) of the FD&C Act states that the PAS fee is equal to half the ANDA fee; therefore the PAS fee is $25,760. We note that the statute provides that those ANDAs that include information about the production of active pharmaceutical ingredients other than by reference to a DMF will pay an additional fee that is based on the number of such active pharmaceutical ingredients and the number of facilities proposed to produce those ingredients. (See section 744B(a)(3)(F) of the FD&C Act.) FDA considers this additional fee to be unlikely to be assessed often; therefore, FDA has not included projections concerning the amount of this fee in calculating the fees for ANDAs and PASs.

IV. DMF Fee

Under GDUFA, the DMF fee is owed by each person that owns a type II active pharmaceutical ingredient drug master file that is referenced, on or after October 1, 2012, in a generic drug submission by an initial letter of authorization. This is a one-time fee for each individual DMF. This fee is due no later than the date on which the first generic drug submission is submitted that references the associated DMF, or 30 days after publication of this notice, whichever is later. (Under section 744B(a)(2)(D)(iii) of the FD&C Act, if the DMF successfully undergoes an initial completeness assessment and the fee is paid, the DMF will be placed on a publicly available list documenting DMFs available for reference. Thus some DMFs holders may choose to pay the fee prior to the date that it would otherwise be due in order to have the DMF placed on that list.) Section 744B(b)(2)(A) of the FD&C Act specifies that the DMF fee will make up 6 percent of the remaining $249,000,000, which is $14,940,000.

In order to calculate the DMF fee, FDA must estimate the number of DMFs that will be referenced by an initial letter of reference in FY 2013. This number will include DMFs that have been referred to in ANDAs prior to FY 2013, but that are first referred to in an initial letter of reference in an ANDA during that year. Based on the numbers of DMFs referenced by ANDAs and PASs in 2011, the last full calendar year for which DMF information is available, FDA is estimating that 700 DMFs will be referenced by an initial letter of reference in FY 2013. Dividing the DMF revenue of $14,940,000 by the estimated number of first-referenced DMFs (700), and rounding to the nearest $10, yields a DMF fee of $21,340 for FY 2013.

V. Fee Payment Options and Procedures

To pay the ANDA, PAS, or DMF fee, you must complete a generic drug user fee cover sheet, available at http://www.fda.gov/gdufa starting in October 2012, and generate a user fee

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 ID number.

Please include the user fee 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 your unique user fee ID number when completing your transfer. The originating financial institution may charge a wire transfer fee. Please ask your financial institution about the fee and include it with your payment to ensure that your 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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