FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 29, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013–18633 Filed 8–1–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Ophthalmic Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Ophthalmic Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 19, 2013, from 8 a.m. to 6 p.m.

Location: Hilton Washington, DC North/Gaithersburg, salons A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel telephone number is 301–977–8900.

Contact Person: Natasha Facey, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1544, Silver Spring, MD 20933, 301–796–5920, *Natasha.Facey@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On September 19, 2013, the committee will discuss, make recommendations, and vote on information regarding the premarket approval application for the ReSure Sealant sponsored by Ocular Therapeutix, Inc. The ReSure Sealant is an in situ formed hydrogel that is applied topically to clear corneal incisions to create an adherent temporary, soft and lubricious sealant. The ReSure Sealant proposed indication for use is the intraoperative management of clear corneal incisions with a wound leak demonstrated by Seidel test, and for prevention of postoperative fluid egress following cataract or intraocular lens placement surgery.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before September 13, 2013. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before September 5, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by September 9, 2013.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams at *Annmarie.Williams@fda.hhs.gov* or 301–796–5966, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 29, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013–18636 Filed 8–1–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0007]

Generic Drug User Fee—Abbreviated New Drug Application, Prior Approval Supplement, Drug Master File, Final Dosage Form Facility, and Active Pharmaceutical Ingredient Facility Fee Rates for Fiscal Year 2014

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 to an approved ANDA (PAS), drug master file (DMF), generic drug active pharmaceutical ingredient (API), and finished dosage form (FDF) facilities user fees related to the Generic Drug User Fee Program for fiscal year (FY) 2014. 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 (only applicable to FY 2013), on FDF and 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, and publish those rates in the **Federal Register** 60 days before the start of the upcoming FY. This document establishes FY 2014 rates for an ANDA ($63,860), PAS ($31,930), DMF ($31,460), domestic API facility ($34,515), foreign API facility ($49,515), domestic FDF facility ($220,152), and foreign FDF facility ($235,152). These fees are effective on October 1, 2013, and will remain in effect through September 30, 2014.

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 (21 U.S.C. 379j-41 and 379j–42) establish fees associated with human generic drug products. Fees are assessed on: (1) Certain applications in the backlog as of October 1, 2012 (only applicable to FY 2013); (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).

II. Fee Revenue Amount for FY 2014

The base revenue amount for FY 2014 is $299,000,000, as set in the statute prior to the inflation adjustment. GDUFA directs FDA to use the yearly revenue amount as a starting point to set the fee rates for each fee type. For more information about GDUFA, please refer to the FDA Web site (*http://www.fda.gov/gdufa*). The ANDA, PAS, DMF, API facility, and FDF facility fee calculations for FY 2014 are described in this document.

Inflation Adjustment

GDUFA specifies that the $299,000,000 is to be further adjusted for inflation increases for FY 2014 using two separate adjustments—one for personnel compensation and benefits (PC&B) and one for non-PC&B costs (see section 744B(c)(1) of the FD&C Act).

The component of the inflation adjustment for PC&B costs shall be one plus the average annual percent change in the cost of all PC&B paid per full-time equivalent position (FTE) at FDA for the first 3 of the 4 preceding FYs, multiplied by the proportion of PC&B costs to total FDA costs of the review of human generic drug activities for the first 3 of the preceding 4 FYs (see section 744B(c)(1)(B) of the FD&C Act). The data on total PC&B paid and numbers of FTE paid, from which the average cost per FTE can be derived, are published in FDA's Justification of Estimates for Appropriations Committees.

Table 1 of this document summarizes the actual cost and total FTE for the specified FYs, and provides the percent change from the previous FY and the average percent change over the first 3 of the 4 FYs preceding FY 2014. The 3-year average is 2.05 percent.

TABLE 1—FDA PERSONNEL COMPENSATION AND BENEFITS (PC&B) EACH YEAR AND PERCENT CHANGE

Fiscal year	2010	2011	2012	3-Year average
Total PC&B	$1,634,108,000	$1,761,655,000	$1,824,703,000	
Total FTE	12,526	13,331	13,382	
PC&B per FTE	$130,457	$132,147	$136,355	
% Change from Previous Year	1.67%	1.30%	3.18%	2.05%

The statute specifies that this 2.05 percent should be multiplied by the proportion of PC&B expended for the review of human generic drug activities. Since the first year of the Generic Drug User Fee Program has not been completed and those costs are not yet available, costs for the entire Agency will be used. Table 2 of this document shows the total amount of expenditures made by FDA broken down by PC&B and Non-PC&B for FYs 2010, 2011, and 2012.

TABLE 2—PC&B AND NON-PC&B AS A PERCENT OF TOTAL EXPENDITURES BY FDA OVER THE LAST 3 YEARS

Fiscal year	2010	2011	2012	3-Year average
PC&B	$1,634,108,000	$1,761,655,000	$1,824,703,000	
Non-PC&B	$1,536,502,000	$1,571,752,000	$1,725,793,000	
Total Costs	$3,170,610,000	$3,333,407,000	$3,550,496,000	
PC&B percent	52%	53%	51%	52%
Non-PC&B percent	48%	47%	49%	48%

The payroll adjustment is 2.05 percent multiplied by 52 percent (or 1.066 percent).

The statute specifies that the portion of the inflation adjustment for non-PC&B costs for FY 2014 is the average annual percent change that occurred in the Consumer Price Index (CPI) for urban consumers (Washington-Baltimore, DC–MD–VA–WV; not seasonally adjusted; all items; annual index) for the first 3 of the preceding 4 years of available data multiplied by the proportion of all costs of the process for the review of human generic drug activities other than PC&B (see section 744B(c)(1)(C) of the FD&C Act). Table 3 of this document provides the summary data for the percent change in the specified CPI for the Baltimore-Washington area. The data are published by the Bureau of Labor Statistics and can be found on their Web site at *http://data.bls.gov/cgi-bin/*

surveymost?cu by checking the box marked ''Washington-Baltimore All Items, November 1996 = 100 − CUURA311SAO'' and then clicking on the ''Retrieve Data'' button.

TABLE 3—ANNUAL AND 3-YEAR AVERAGE PERCENT CHANGE IN BALTIMORE-WASHINGTON AREA CPI

Year	2010	2011	2012	3-Year average
Annual CPI	142.218	146.975	150.212	
Annual Percent Change	1.72%	3.34%	2.20%	2.42%

To calculate the inflation adjustment for non-pay costs, we multiply the 2.42 percent by the proportion of costs FDA obligated for costs other than PC&B. Since 52 percent was obligated for PC&B as shown in table 2 of this document, 48 percent is the portion of costs other than PC&B. The non-pay adjustment is 2.42 percent times 48 percent, or 1.161 percent.

To complete the inflation adjustment, we add the PC&B component (1.066 percent) to the non-PC&B component (1.161 percent) for a total inflation adjustment of 2.227 percent (rounded), and then add one, making 1.02227. We then multiply the base revenue amount for FY 2014 ($299,000,000) by 1.02227, yielding an inflation adjusted amount of $305,659,000 (rounded to the nearest thousand dollars).

III. ANDA and PAS Fees

Under GDUFA, the FY 2014 ANDA and PAS fees are owed by each applicant that submits an ANDA or a PAS, on or after October 1, 2013. These fees are due on the receipt date of the ANDA or PAS. Section 744B(b)(2)(B) specifies that the ANDA and PAS fees will make up 24 percent of the $305,659,000, which is $73,358,000 (rounded to the nearest thousand dollars).

In order to calculate the ANDA fee, FDA estimated the number of full application equivalents (FAEs) that will be submitted in FY 2014. This is done by estimating the number of ANDAs and PASs that will incur the fee in FY 2014 and converting them into 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. However, GDUFA requires that 75 percent of the fees paid for an ANDA or PAS filing fee 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 ANDA or PAS 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 paid the supplement fee (one half of the full application fee amount).

It was determined that approximately 911 ANDAs will incur an ANDA filing fee in FY 2014. This number is based on available data from the first 8 months of FY 2013 and estimating the last 4 months based on the current trend. In contrast to previous non-fee paying FYs, the first year of GDUFA implementation saw a significant increase in Changes Being Effected (CBE) submissions and a significant decrease in PAS submissions. Due to the trend of FY 2013 submissions, FDA utilized available FY 2013 data to estimate the number of such supplement submissions for FY 2014. The estimated number of PASs to be received in FY 2014 is 480, based on an annualized estimate of the number of receipts for FY 2013.

After 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 2014 is 1,148.8.

The FY 2014 application fee is estimated by dividing the number of full application equivalents that will pay the fee in FY 2014 (1,148.8) into the fee revenue amount to be derived from application fees in FY 2014 ($73,358,000). The result, rounded to the nearest $10, is a fee of $63,860 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 $31,930.

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 that this additional fee is 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 DMF 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. Under section 744B(a)(2)(D)(iii) of the FD&C Act, if a DMF has successfully undergone 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 DMF 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.

In order to calculate the DMF fee, FDA assessed the volume of DMF submissions over time. The statistical forecasting methodology of power regression analysis was selected because this model showed a very good fit to the distribution of DMF submissions over time. Based on the 8 months of available data representing the total paid DMFs from FY 2013 and projecting a 5-year timeline (October 2013 to October 2017), FDA is estimating 583 fee-paying DMFs for FY 2014.

The FY 2014 DMF fee is determined by dividing the DMF revenue by the estimated number of fee-paying DMFs in FY 2014. Section 744B(b)(2)(A) specifies that the DMF fees will make up 6 percent of the $305,659,000, which is $18,340,000 (rounded to the nearest thousand dollars). Dividing the DMF revenue amount ($18,340,000) by the estimated fee-paying DMFs (583), and rounding to the nearest $10, yields a DMF fee of $31,460 for FY 2014.

V. Foreign Facility Fee 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 2014 FDA has determined that the differential for foreign facilities will be $15,000. The differential may be adjusted in future years.

VI. 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 a human generic drug or an active pharmaceutical ingredient used in a human generic drug. These fees are due no later than the first business day on or after October 1 of each such year. Section 744B(b)(2)(C) of the FD&C Act specifies that the FDF facility fee revenue will make up 56 percent of $305,659,000, which is $171,169,000 (rounded to the nearest thousand dollars).

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 748. Of the total facilities identified as FDF, there were 315 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 ($171,169,000) results in a remaining fee revenue balance of $164,674,000. To determine the domestic FDF facility fee, we divide the $164,674,000 by the total number of facilities (748) which gives us a domestic FDF facility fee of $220,152. The foreign FDF facility fee is $15,000 more than the domestic FDF facility fee, or $235,152.

VII. 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 the first business day on or after October 1 of each such year. Section 744B(b)(2)(D) of the FD&C Act specifies that the API facility fee will make up 14 percent of $305,659,000 in fee revenue, which is $42,792,000 (rounded to the nearest thousand dollars).

In order to calculate the API fee, FDA has used the data submitted by generic drug facilities through the self-identification process. The total number of API facilities identified through self-identification was 903. Of the total facilities identified as API, there were 128 domestic facilities and 775 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 (775) 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 $11,625,000 of the total API fee revenue. Subtracting the foreign facility differential fee revenue ($11,625,000) from the total API facility target revenue ($42,792,000) results in a remaining balance of $31,167,000. To determine the domestic API facility fee, we divide the $31,167,000 by the total number of facilities (903) which gives us a domestic API facility fee of $34,515. The foreign API facility fee is $15,000 more than the domestic API facility fee, or $49,515.

VIII. Fee Payment Options and Procedures

The new fee rates are effective October 1, 2013. To pay the ANDA, PAS, DMF, API facility, and FDF facility fee, you must complete a Generic Drug User Fee cover sheet, available at *http://www.fda.gov/gdufa*, 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 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 FDA is 53–0196965.

Dated: July 29, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–18625 Filed 8–1–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0007]

Prescription Drug User Fee Rates for Fiscal Year 2014

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates for prescription drug user fees for