link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On October 13, 2016, the committee will meet in open session to discuss and make recommendations on the selection of strains to be included in an influenza virus vaccine for the 2017 southern hemisphere influenza season.

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 October 3, 2016. Oral presentations from the public will be scheduled between approximately 2:30 p.m. and 3:30 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 23, 2016. 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 26, 2016.

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 disabilities. If you require accommodations due to a disability, please contact Sujata Vijh 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 21, 2016.

Janice M. Soreth,

Acting Associate Commissioner, Special Medical Programs.

[FR Doc. 2016–17729 Filed 7–26–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–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 2017

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates for abbreviated new drug applications (ANDAs), prior approval supplements to an approved ANDA (PASs), drug master files (DMFs), generic drug active pharmaceutical ingredient (API) facilities, and finished dosage form (FDF) facilities user fees related to the Generic Drug User Fee Program for fiscal year (FY) 2017. 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 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. This document establishes the fee rates for FY 2017.

FOR FURTHER INFORMATION CONTACT: David Haas, Office of Financial Management, Food and Drug Administration, 8455 Colesville Rd., COLE–14202I, Silver Spring, MD 20993–0002, 240–402–9845.

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 (see section 744B(a)(1)–(4) of the FD&C Act).

For FY 2017, the generic drug fee rates are: ANDA ($70,480), PAS ($35,240), DMF ($51,140), domestic API facility ($44,234), foreign API facility ($59,234), domestic FDF facility ($258,646), and foreign FDF facility ($273,646). These fees are effective on October 1, 2016, and will remain in effect through September 30, 2017.

Fees for ANDA and PAS will decrease in FY 2017 compared to the FY 2016 fees due to an increase in the number of submissions estimated to be submitted in FY 2017 compared to the estimated number of submissions to be submitted in FY 2016. Fees for DMFs will increase in FY 2017 compared to the FY 2016 fee due to a decrease in the number of submissions estimated to be submitted in FY 2017 compared to the estimated number of submissions to be submitted in 2016. The fees for all types of facilities will increase in FY 2017 compared to the FY 2016 fees in due to a decrease in the number of facilities that self-identified for FY 2017.

II. Fee Revenue Amount for FY 2017

The base revenue amount for FY 2017 is $299 million, as set in the statute prior to the inflation and final year adjustments (see section 744B(c)(2) of the FD&C Act). 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 2017 are described in this document.

A. Inflation Adjustment

GDUFA specifies that the $299 million is to be adjusted for inflation increases for FY 2017 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 three of the four preceding fiscal years, multiplied by the proportion of PC&B costs to total FDA costs of human generic drug activities for the first three of the preceding four fiscal years (see section 744B(c)(1)(A)–(B) of the FD&C Act).

Table 1 summarizes the actual cost and total FTE for the specified fiscal years, and provides the percent change from the previous fiscal year and the average percent change over the first three of the four fiscal years preceding FY 2017. The 3-year average is 1.8759 percent.

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

Fiscal year	2013	2014	2015	3-Year average
Total PC&B	$1,927,703,000	$2,054,937,000	$2,232,304,000	.....
Total FTE	13,974	14,555	15,484	.....
PC&B per FTE	$137,949	$141,184	$144,168	.....
% Change from Previous Year	1.1690%	2.3451%	2.1136%	1.8759%

The statute specifies that this 1.8759 percent should be multiplied by the proportion of PC&B expended for human generic drug activities for the first three of the preceding four fiscal years. Table 2 shows the amount of PC&B and the total amount obligated for human generic drug activities from FY 2013 through FY 2015.

TABLE 2—PC&B AS A PERCENT OF FEE REVENUES SPENT ON THE PROCESS OF HUMAN GENERIC DRUG APPLICATIONS OVER THE LAST 3 YEARS

Fiscal year	2013	2014	2015	3-Year average
PC&B	$117,576,760	$171,612,147	$201,116,305	.....
Non-PC&B	$149,307,336	$215,469,132	$251,589,013	.....
Total Costs	$266,884,096	$387,081,279	$452,705,318	.....
PC&B percent	44.0554%	44.3349%	44.4254%	44.2719%
Non-PC&B percent	55.9446%	55.6651%	55.5746%	55.7281%

The payroll adjustment is 1.8759 percent multiplied by 44.2719 percent (or 0.8305 percent).

The statute specifies that the portion of the inflation adjustment for non-PC&B costs for FY 2017 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 three of the preceding four years of available data multiplied by the proportion of all costs other than PC&B costs to total costs of human generic drug activities (see section 744B(c)(1)(C) of the FD&C Act). Table 3 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—CUURA311SA0'' and then clicking on the ''Retrieve Data'' button.

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

Year	2013	2014	2015	3-Year average
Annual CPI	152.500	154.847	155.353	.....
Annual Percent Change	1.5232%	1.5390%	0.3268%	1.1297%

To calculate the inflation adjustment for non-pay costs, we multiply the 3-year average percent change in the CPI (1.1297 percent) by the proportion of all costs other than PC&B to total costs of human generic drug activities obligated. Since 44.2719 percent was obligated for PC&B as shown in Table 2, 55.7281 percent is the portion of costs other than PC&B. The non-pay adjustment is 1.1297 percent times 55.7281 percent, or 0.6296 percent.

To complete the inflation adjustment for FY 2017, we add the PC&B component (0.8305 percent) to the non-PC&B component (0.6296 percent) for a total inflation adjustment of 1.4601 percent (rounded) for FY 2017.

GDUFA provides for this inflation adjustment to be compounded after FY 2013 (see section 744B(c)(1) of the FD& C Act). This factor for FY 2017 (1.4601 percent) is compounded by adding one to it, and then multiplying it by the compounded inflation adjustment factor for FY 2016 (1.064759), as published in the **Federal Register** of August 3, 2015 (80 FR 46015). The result of this multiplication of the inflation factors for the four years since FY 2013 (1.014601 times 1.064759 percent) becomes the inflation adjustment for FY 2017. For FY 2017, the inflation adjustment is 8.0306 percent (rounded). We then add one, making 1.080306. Finally, we multiply the FY 2017 base revenue amount ($299 million) by 1.080306, yielding inflation-adjusted target revenue of $323,011,000 (rounded to the nearest thousand dollars).

B. Final Year Adjustment

For FY 2017, the Secretary may, in addition to the inflation adjustment, further increase the fee revenues and fees established if such an adjustment is necessary to provide for not more than 3 months of operating reserves of carryover user fees for human generic drug activities for the first 3 months of FY 2018. Such fees may only be used in FY 2018. If such an adjustment is necessary, the rationale for the amount of the increase shall be contained in the

annual notice establishing fee revenues and fees for FY 2017. If the Secretary has carryover balances for such activities in excess of 3 months of such operating reserves, the adjustment shall not be made (see section 744B(c)(2) of the FD&C Act).

After running analyses on the status of GDUFA's operating reserves and its estimated balance as of the beginning of FY 2018, FDA estimates that the GDUFA program will have carryover balances for such activities in excess of 3 months of such operating reserves, thus FDA will not be performing a final year adjustment.

III. ANDA and PAS Fees

Under GDUFA, the FY 2017 ANDA and PAS fees are owed by each applicant that submits an ANDA or a PAS, on or after October 1, 2016. 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 $323,011,000, which is $77,523,000 (rounded to the nearest thousand dollars), and further specifies that the PAS fee is equal to half the ANDA fee.

In order to calculate the ANDA fee, FDA estimated the number of full application equivalents (FAEs) that will be submitted in FY 2017. This is done by assuming ANDAs count as one FAE and PASs (supplements) count as one-half an FAE since the fee for a PAS is one half of the fee for an ANDA. GDUFA also requires, however, that 75 percent of the fee paid for an ANDA or PAS filing fee be refunded if the ANDA or PAS 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).

FDA utilized data from ANDAs and PASs submitted from October 1, 2013, to May 31, 2016, to estimate the number of new original ANDAs and PASs that will incur filing fees in FY 2017. For FY 2017, the Agency estimates that approximately 891 new original ANDAs and 439 PASs will be submitted and incur filing fees. Not all of the new original ANDAs and PASs will be received by the Agency, and some of those not received will be resubmitted in the same fiscal year. Therefore, the Agency expects that the FAE count for ANDAs and PASs will be 1,100 for FY 2017.

The FY 2017 application fee is estimated by dividing the number of FAEs that will pay the fee in FY 2017 (1,100) into the fee revenue amount to be derived from application fees in FY 2017 ($77,523,000). The result, rounded to the nearest $10, is a fee of $70,480 per ANDA. The PAS fee is one-half that amount, or $35,240, rounded to the nearest $10.

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 data representing the total paid DMFs from October 2013 to May 2016 and projecting a 5-year timeline (October 2013 to September 2018), FDA is estimating 379 fee-paying DMFs for FY 2017.

The FY 2017 DMF fee is determined by dividing the DMF target revenue by the estimated number of fee-paying DMFs in FY 2017. Section 744B(b)(2)(A) specifies that the DMF fees will make up six percent of the $323,011,000, which is $19,381,000 (rounded to the nearest thousand dollars). Dividing the DMF revenue amount ($19,381,000) by the estimated fee-paying DMFs (379), and rounding to the nearest $10, yields a DMF fee of $51,140 for FY 2017.

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 2017, FDA has determined that the differential for foreign facilities will be $15,000.

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. 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 $323,011,000, which is $180,886,000 (rounded to the nearest thousand dollars).

In order to calculate the FDF fee, FDA used 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 (77 FR 60125). The total number of FDF facilities identified through self-identification was 675. Of the total facilities identified as FDF, there were 255 domestic facilities and 420 foreign facilities. The foreign facility fee 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 (420) 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 $6,300,000 of the total FDF fee revenue. Subtracting the foreign facility differential fee revenue ($6,300,000), from the total FDF facility target revenue ($180,886,000) results in a remaining fee revenue balance of $174,586,000. To determine the

domestic FDF facility fee, we divide the $174,586,000 by the total number of facilities (675) which results in a domestic FDF facility fee of $258,646. The foreign FDF facility fee is $15,000 more than the domestic FDF facility fee, or $273,646.

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 $323,011,000 in fee revenue, which is $45,221,000 (rounded down to the nearest thousand dollars).

In order to calculate the API fee, FDA used 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 API facilities identified through self-identification was 789. Of the total facilities identified as API facilities, there were 101 domestic facilities and 688 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 (688) 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 $10,320,000 of the total API fee revenue. Subtracting the foreign facility differential fee revenue ($10,320,000) from the total API facility target revenue ($45,221,000) results in a remaining balance of $34,901,000. To determine the domestic API facility fee, we divide the $34,901,000 by the total number of facilities (789) which gives us a domestic API facility fee of $44,234. The foreign API facility fee is $15,000 more than the domestic API facility fee, or $59,234.

VIII. Fee Schedule for FY 2017

The fee rates for FY 2017 are set out in Table 4.

TABLE 4—FEE SCHEDULE FOR FY 2017

Fee category	Fee rates for FY 2017
Applications:	
Abbreviated New Drug Application (ANDA)	$70,480
Prior Approval Supplement (PAS) to an ANDA	35,240
Drug Master File (DMF)	51,140
Facilities:	
Active Pharmaceutical Ingredient (API)—Domestic	44,234
API—Foreign	59,234
Finished Dosage Form (FDF)—Domestic	258,646
FDF—Foreign	273,646

IX. Fee Payment Options and Procedures

The new fee rates are effective October 1, 2016. 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. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay.* Once you search for your invoice, click ''Pay Now'' to be redirected to *Pay.gov*. Note that electronic payment options are based on the balance due. Payment by credit card is available for balances less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be drawn on U.S. bank accounts as well as U.S. credit cards.

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. If you have any questions concerning courier delivery contact the U.S. Bank at 314–418–4013. This telephone number is only for questions about courier delivery). 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 wire transfer fee and include it with your payment to ensure that your fee is fully paid. The account information is as follows: U.S. Department of Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, account number: 75060099, routing number: 021030004, SWIFT: FRNYUS33, Beneficiary: FDA, 8455 Colesville Rd., 14th Floor, Silver Spring, MD 20993–0002. The tax identification number of FDA is 53–0196965.

Dated: July 22, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–17801 Filed 7–26–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–2153]

Use of Real-World Evidence to Support Regulatory Decisionmaking for Medical Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''Use of Real-World Evidence to Support Regulatory Decisionmaking for Medical Devices.'' FDA is issuing this draft guidance to clarify how we evaluate real-world data (RWD) to determine whether it may be sufficiently relevant and reliable to generate the types of real-world evidence that can be used in regulatory decisionmaking for medical devices. This guidance also clarifies when an