

submission by the sponsor of an IND describing an investigation that FDA determines is intended to support a biosimilar biological product application.

The application fee for a biosimilar biological product is due upon submission of the application (see section 744H(a)(2)(C) of the FD&C Act).

To make a payment of the initial BPD, reactivation, or application fee, complete the Biosimilar User Fee Cover Sheet, available on FDA's Web site (<http://www.fda.gov/bsufa>) and generate a user fee identification (ID) number. Payment must be made in U.S. currency 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> (Note: Only full payments are accepted. No partial payments can be made online). Once you search for your invoice, click "Pay Now" to be redirected to Pay.gov. Electronic payment options are based on the balance due. Payment by credit card is available for balances that are less than \$25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

FDA has partnered with the U.S. Department of the Treasury to use <http://www.pay.gov>, a web-based payment application, for online electronic payment. The Pay.gov feature is available on FDA's Web site after completing the Biosimilar 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 it payable to the Food and Drug Administration. Your payment can be mailed to: Food and Drug Administration, P.O. Box 979108, St. Louis, MO 63197-9000. To send a check by a courier such as Federal Express or United Parcel Service, the courier must deliver the check and printed copy of the cover sheet to: U.S. Bank, ATTN: Government Lockbox 979108, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This U.S. Bank address is for courier delivery only. Contact U.S. Bank at 314-418-4013 if you have any questions concerning 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 the 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 for wire transfers is as follows: U.S. Department of Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No.: 75060099, Routing No.: 021030004, SWIFT: FRNYUS33, Beneficiary: FDA, 8455 Colesville Rd., 14th Floor, Silver Spring, MD 20993-0002. If needed, FDA's tax identification number is 53-0196965.

B. Annual BPD and Program Fees

FDA will issue invoices for annual BPD and program fees for FY 2018 under the new fee schedule in September 2017. Payment instructions will be included in the invoices, including payment due dates. If sponsors join the BPD program after the annual BPD invoices have been issued in September 2017, FDA will issue invoices in December 2017 to firms subject to fees for FY 2018 that qualify for the annual BPD fee after the September 2017 billing. FDA will issue invoices in December 2017 for any annual program fees for FY 2018 that qualify for fee assessments and were not issued in September 2017.

Dated: September 8, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0594]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Focus Groups as Used by the Food and Drug Administration (All Food and Drug Administration-Regulated Products)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by October 16, 2017.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0497. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance. Focus Groups as Used by the Food and Drug Administration (All FDA-Regulated Products), OMB Control Number 0910-0497.

FDA conducts voluntary focus group interviews on a variety of topics involving FDA-regulated products, including drugs, biologics, devices, food, tobacco, and veterinary medicine.

Focus groups provide an important role in gathering information because they allow for a more in-depth understanding of patients' and consumers' attitudes, beliefs, motivations, and feelings than do quantitative studies. Focus groups serve the narrowly defined need for direct and informal opinion on a specific topic and as a qualitative research tool have three major purposes:

- To obtain patient and consumer information that is useful for developing variables and measures for quantitative studies,

- To better understand patients' and consumers' attitudes and emotions in response to topics and concepts, and
- To further explore findings obtained from quantitative studies.

FDA will use focus group findings to test and refine their ideas, but will generally conduct further research before making important decisions such as adopting new policies and allocating or redirecting significant resources to support these policies.

In the **Federal Register** of April 21, 2017 (82 FR 18763), FDA published a 60-day notice requesting public comment on the proposed collection of

information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Focus Group Interviews	8,800	1	8,800	1.75	15,400

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: September 8, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017-19492 Filed 9-13-17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-0007]

Prescription Drug User Fee Rates for Fiscal Year 2018

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 fiscal year (FY) 2018. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Prescription Drug User Fee Amendments of 2017 (PDUFA VI), authorizes FDA to collect application fees for certain applications for the review of human drug and biological products, and prescription drug program fees for certain approved products. This notice establishes the fee rates for FY 2018.

FOR FURTHER INFORMATION CONTACT: Robert J. Marcarelli, Office of Financial Management, Food and Drug Administration, 8455 Colesville Rd., COLE-14202F, Silver Spring, MD 20993-0002, 301-796-7223.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 735 and 736 of the FD&C Act (21 U.S.C. 379g and 379h, respectively)

establish two different kinds of user fees. Fees are assessed on the following: (1) Application fees are assessed on certain types of applications for the review of human drug and biological products; and (2) prescription drug program fees are assessed on certain approved products (section 736(a) of the FD&C Act). When specific conditions are met, FDA may waive or reduce fees (section 736(d) of the FD&C Act).

For FY 2018 through FY 2022, the base revenue amounts for the total revenues from all PDUFA fees are established by PDUFA VI. The base revenue amount for FY 2018 is \$878,590,000. The FY 2018 base revenue amount is to be adjusted for inflation and for the resource capacity needs for the process for the review of human drug applications (the capacity planning adjustment). An additional dollar amount specified in the statute (see section 736(b)(1)(F) of the FD&C Act) is then added to provide for additional full-time equivalent (FTE) positions to support PDUFA VI initiatives. The FY 2018 revenue amount may be adjusted further, if necessary, to provide for sufficient operating reserves of carryover user fees. Finally, the amount is adjusted to provide for additional direct costs to fund PDUFA VI initiatives. Fee amounts are to be established each year so that revenues from application fees provide 20 percent of the total revenue, and prescription drug program fees provide 80 percent of the total revenue.

This document provides fee rates for FY 2018 for an application requiring clinical data (\$2,421,495), for an application not requiring clinical data (\$1,210,748), and for the prescription

drug program fee (\$304,162). These fees are effective on October 1, 2017, and will remain in effect through September 30, 2018. For applications that are submitted on or after October 1, 2017, the new fee schedule must be used.

II. Fee Revenue Amount for FY 2018

The base revenue amount for FY 2018 is \$878,590,000 prior to adjustments for inflation, capacity planning, additional FTE, operating reserve, and additional direct costs (see section 736(b)(1) of the FD&C Act).

A. FY 2018 Statutory Fee Revenue Adjustments for Inflation

PDUFA VI specifies that the \$878,590,000 is to be adjusted for inflation increases for FY 2018 using two separate adjustments—one for personnel compensation and benefits (PC&B) and one for non-PC&B costs (see section 736(c)(1) of the FD&C Act).

The component of the inflation adjustment for payroll costs shall be one plus the average annual percent change in the cost of all PC&B paid per FTE positions at FDA for the first three of the preceding four FYs, multiplied by the proportion of PC&B costs to total FDA costs of the process for the review of human drug applications for the first three of the preceding four FYs (see section 736(c)(1)(A) and (c)(1)(B) of the FD&C Act).

Table 1 summarizes the actual cost and FTE data for the specified FYs and provides the percent changes from the previous FYs and the average percent changes over the first three of the four FYs preceding FY 2018. The 3-year average is 2.2354 percent.

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

Fiscal year	2014	2015	2016	3-year average
Total PC&B	\$2,054,937,000	\$2,232,304,000	\$2,414,728,159	
Total FTE	14,555	15,484	16,381	
PC&B per FTE	\$141,184	\$144,168	\$147,408	
Percent Change From Previous Year	2.3451	2.1136	2.2474	2.2354