C. Fee Payment Procedures

1. 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 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.

2. If paying with a paper check: Checks must be in U.S. currency from a U.S. bank and made payable to the Food and Drug Administration. Payments can be mailed to: Food and Drug Administration, P.O. Box 979033, St. Louis, MO 63197–9000. If a check is sent by a courier that requests a street address, the courier can deliver the check to: U.S. Bank, Attn: Government Lockbox 979033, 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).

3. When paying by wire transfer, the invoice number must be included. Without the invoice number the payment may not be applied. Regarding re-inspection fees, if the payment amount is not applied, the invoice amount will be referred to collections. The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee, it is required that the outsourcing facility add that amount to the payment to ensure that the invoice is paid in full. Use the following account information when sending a wire transfer: New York Federal Reserve Bank, U.S. Dept 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.

Dated: July 25, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–16185 Filed 8–1–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Over-the-Counter Monograph User Fees: Stakeholder Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) will hold a webinar for stakeholders on August 23, 2017, to provide stakeholders with a status update on the process of FDA and industry discussions on an Over-the-Counter (OTC) Monograph user fee program that began in July 2016. FDA will also provide an overview of proposed performance goals and procedures related to a potential new OTC monograph user fee program. This webinar is intended to be a followup to the June 10, 2016, public meeting and the September 6, 2016, stakeholder webinar on a potential new OTC monograph user fee program.

DATES: FDA will hold a webinar for stakeholders on Wednesday, August 23, 2017, from 12:30 p.m. to 2 p.m. EDT.

FOR FURTHER INFORMATION CONTACT: Mary Vienna, Office of Executive Programs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903–0002, 301–796–4150, email: *OTCMonographUserFeeProgram@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

On June 10, 2016, FDA held a public meeting on a potential new user fee program for nonprescription (over-the-counter or OTC) monograph drugs. In the announcement of the public meeting in the **Federal Register** (May 11, 2016, 81 FR 29275), FDA invited public comment as the Agency considers a user-fee program for OTC monograph drugs. A user-fee program would provide funding to supplement congressional non-user-fee appropriations, and would support timely and efficient FDA review of the efficacy and safety of ingredients included in or proposed for inclusion in a monograph. Interested persons were given until July 11, 2016, to submit comments. A stakeholder webinar was held on September 6, 2016, which provided stakeholders with a status update on the process of FDA and industry discussions that began in July 2016. In the notice of public meeting (August 8, 2016, 81 FR 52444), FDA invited public comments and interested parties were given until October 6, 2016, to submit comments.

FDA will hold a webinar for stakeholders on August 23, 2017, to provide stakeholders with a status update on the process of FDA and industry discussions on an OTC Monograph user fee program that began in July 2016. FDA will also provide an overview of proposed performance goals and procedures related to a potential new OTC monograph user fee program. This webinar is intended to be a followup to the June 10, 2016, public meeting and the September 6, 2016, stakeholder webinar on a potential new OTC monograph user fee program.

II. Background

Meeting minutes from FDA and industry discussions on a new OTC monograph user fee program can be found at: *https://www.fda.gov/ForIndustry/UserFees/OTCMonographUserFee/default.htm.* The proposed OTC Monograph User Fee Program Performance Goals and Procedures—Fiscal Years 2018–2022 document can also be found at that same Web site.

Additional background information on OTC monograph drugs (such as how OTC drugs can be marketed, and the differences between marketing through approved applications and marketing under the monographs), factors FDA considers important in developing a user-fee program, and the questions for which FDA asked the public to consider and provide input, can be found in the **Federal Register** notice from the June 10, 2016, public meeting (*https://www.federalregister.gov/articles/2016/05/11/2016-11098/over-the-counter-monograph-user-fees-public-meeting-request-for-comments*). The meeting transcript, meeting recording, and presentations from the June 10, 2016, public meeting, which can serve as further background information, can be found at: *https://www.fda.gov/ForIndustry/UserFees/OTCMonographUserFee/default.htm.* A summary of the September 6, 2016, stakeholders' webinar, can also be found at: *https://www.fda.gov/ForIndustry/UserFees/OTCMonographUserFee/default.htm.*

III. Stakeholder Meeting Participation

FDA is seeking participation at the webinar by stakeholders, including scientific and academic experts, health care professionals, representatives of patient and consumer advocacy groups, and representatives of the OTC monograph industry. Participating in the webinar is free. The webinar format

will include presentations by FDA staff and an opportunity for stakeholders to ask questions. If you wish to attend the webinar, FDA asks that you please register through Eventbrite by 12 a.m. EDT, Saturday, August 19, 2017: *https://www.eventbrite.com/e/over-the-counter-monograph-user-fees-stakeholder-meeting-registration-33593404778*. FDA will email the registered attendees a URL to join the webinar at least 1 day before the meeting.

Dated *July 27, 2017.*

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–16229 Filed 8–1–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0007]

Animal Drug User Fee Rates and Payment Procedures for Fiscal Year 2018

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates and payment procedures for fiscal year (FY) 2018 animal drug user fees. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Animal Drug User Fee Amendments of 2013 (ADUFA III), authorizes FDA to collect user fees for certain animal drug applications and supplements, for certain animal drug products, for certain establishments where such products are made, and for certain sponsors of such animal drug applications and/or investigational animal drug submissions. This notice establishes the fee rates for FY 2018.

FOR FURTHER INFORMATION CONTACT: Visit FDA's Web site at *http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/default.htm* or contact Lisa Kable, Center for Veterinary Medicine (HFV–10), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–6888. For general questions, you may also email the Center for Veterinary Medicine (CVM) at: *cvmadufa@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 740 of the FD&C Act (21 U.S.C. 379j–12) establishes four different types of user fees: (1) Fees for certain types of animal drug applications and supplements; (2) annual fees for certain animal drug products; (3) annual fees for certain establishments where such products are made; and (4) annual fees for certain sponsors of animal drug applications and/or investigational animal drug submissions (21 U.S.C. 379j–12(a)). When certain conditions are met, FDA will waive or reduce fees (21 U.S.C. 379j–12(d)).

For FY 2014 through FY 2018, the FD&C Act establishes aggregate yearly base revenue amounts for each fiscal year (21 U.S.C. 379j–12(b)(1)). Base revenue amounts established for years after FY 2014 are subject to adjustment for inflation and workload (21 U.S.C. 379j–12(c)). Fees for applications, establishments, products, and sponsors are to be established each year by FDA so that the percentages of the total revenue that are derived from each type of user fee will be as follows: Revenue from application fees shall be 20 percent of total fee revenue; revenue from product fees shall be 27 percent of total fee revenue; revenue from establishment fees shall be 26 percent of total fee revenue; and revenue from sponsor fees shall be 27 percent of total fee revenue (21 U.S.C. 379j–12(b)(2)).

For FY 2018, the animal drug user fee rates are: $238,100 for an animal drug application; $119,050 for a supplemental animal drug application for which safety or effectiveness data are required and for an animal drug application subject to the criteria set forth in section 512(d)(4) of the FD&C Act (21 U.S.C. 360b(d)(4)); $6,175 for an annual product fee; $88,750 for an annual establishment fee; and $75,150 for an annual sponsor fee. FDA will issue invoices for FY 2018 product, establishment, and sponsor fees by December 31, 2017, and payment will be due by January 31, 2018. The application fee rates are effective for applications submitted on or after October 1, 2017, and will remain in effect through September 30, 2018. Applications will not be accepted for review until FDA has received full payment of application fees and any other animal drug user fees owed under the Animal Drug User Fee program (ADUFA program).

II. Revenue Amount for FY 2018

A. Statutory Fee Revenue Amounts

ADUFA III, Title I of Public Law 113–14, specifies that the aggregate fee revenue amount for FY 2018 for all animal drug user fee categories is $21,600,000 (21 U.S.C. 379j–12(b)(1)(B)).

B. Inflation Adjustment to Fee Revenue Amount

The fee revenue amount established in ADUFA III for FY 2015 and subsequent fiscal years are subject to an inflation adjustment (21 U.S.C. 379j–12(c)(2)).

The component of the inflation adjustment for payroll costs shall be one plus the average annual percent change in the cost of all personnel compensation and benefits (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 for the first three of the four preceding fiscal years (see 21 U.S.C. 379j–12(c)(2)(A) and (B)). 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 summarizes that actual cost and FTE data for the specified fiscal years, and provides the percent change from the previous fiscal year and the average percent change over the first of the 4 fiscal years preceding FY 2018. The 3-year average is 2.2354 percent.

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

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%