

approval under section 571 of the FD&C Act for the same product and paid an application fee at the time they applied for conditional approval, provided the sponsor has submitted the application under section 512(b)(1) of the FD&C Act within the timeframe specified in section 571(h) of the FD&C Act.

## IX. Procedures for Paying the FY 2020 Fees

### A. Application Fees and Payment Instructions

The appropriate application fee established in the new fee schedule must be paid for an animal drug application or supplement subject to fees under ADUFA IV that is submitted on or after October 1, 2019. The payment must be made in U.S. currency by one of the following methods: Wire transfer, electronic check, bank draft, or U.S. postal money order made payable to FDA. 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>, or the *Pay.gov* payment option is available after you submit a cover sheet. (Note: Only full payments are accepted. No partial payments can be made online.) Once you search for and find your invoice, select "Pay Now" to be redirected to <https://www.pay.gov/>. Electronic payment options are based on the balance due. Payment by credit card is available only 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.

When paying by check, bank draft, or U.S. postal money order, please write your application's unique Payment Identification Number (PIN), beginning with the letters AD, on the upper right-hand corner of your completed Animal Drug User Fee Cover Sheet. Also write the FDA post office box number (P.O. Box 979033) on the enclosed check, bank draft, or money order. Mail the payment and a copy of the completed Animal Drug User Fee Cover Sheet to: Food and Drug Administration, P.O. Box 979033, St. Louis, MO 63197-9000. When paying by wire transfer, the invoice number needs to be included. Without the invoice number, the payment may not be applied. If the payment amount is not applied, the invoice amount would 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 to add that amount to the payment to ensure that the invoice is paid in full.

Use the following account information when sending a payment by wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, FDA deposit account number: 75060099, U.S. Department of the Treasury routing/transit number: 021030004, SWIFT number: FRNYUS33.

To send a check by a courier such as Federal Express, the courier must deliver the check and printed copy of the cover sheet to: U.S. Bank, Attn: Government Lockbox 979033, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. If you have any questions concerning courier delivery, contact U.S. Bank at 314-418-4013. This telephone number is only for questions about courier delivery.)

It is important that the fee arrives at the bank at least a day or two before the application arrives at CVM. FDA records the official application receipt date as the later of the following: The date the application was received by CVM, or the date U.S. Bank notifies FDA that your payment in the full amount has been received, or when the U.S. Treasury notifies FDA of receipt of an electronic or wire transfer payment. U.S. Bank and the U.S. Treasury are required to notify FDA within 1 working day, using the PIN described previously.

FDA's tax identification number is 53-0196965. (Note: In no case should the payment for the fee be submitted to FDA with the application.)

### B. Application Cover Sheet Procedures

Step One—Create a user account and password. Log on to the ADUFA website at <https://www.fda.gov/industry/animal-drug-user-fee-act-adufa/animal-drug-user-fee-cover-sheet> and, under Application Submission Information, click "Create ADUFA User Fee Cover Sheet." For security reasons, each firm submitting an application will be assigned an organization identification number, and each user will also be required to set up a user account and password the first time they use this site. Online instructions will walk you through this process.

Step Two—Create an Animal Drug User Fee Cover Sheet, transmit it to FDA, and print a copy. After logging into your account with user name and password, complete the steps required to create an Animal Drug User Fee Cover Sheet. One cover sheet is needed for each animal drug application or

supplement. Once you are satisfied that the data on the cover sheet are accurate and you have finalized the cover sheet, you will be able to transmit it electronically to FDA and you will be able to print a copy of your cover sheet showing your unique PIN.

Step Three—Send the payment for your application as described in section IX.A of this document.

Step Four—Please submit your application and a copy of the completed Animal Drug User Fee Cover Sheet to the following address: Food and Drug Administration, Center for Veterinary Medicine, Document Control Unit (HFV-199), 7500 Standish Pl., Rockville, MD 20855.

### C. Product, Establishment, and Sponsor Fees

By December 31, 2019, FDA will issue invoices and payment instructions for product, establishment, and sponsor fees for FY 2020 using this fee schedule. Payment will be due by January 31, 2020. FDA will issue invoices in November 2020 for any products, establishments, and sponsors subject to fees for FY 2020 that qualify for fees after the December 2019 billing.

Dated: July 29, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Notice To Announce Supplemental Awards To Support Technical Assistance To Address the HIV Epidemic

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services.

**ACTION:** Notice to announce supplemental awards to support technical assistance to address the HIV epidemic.

**SUMMARY:** HRSA provided supplemental grant funds to two currently funded National Training and Technical Assistance Cooperative Agreement award recipients to support ending the HIV epidemic by providing critical expertise and resources to health centers in geographic locations identified in Ending the HIV Epidemic: A Plan for America.

**FOR FURTHER INFORMATION CONTACT:** Tracey Orloff, Strategic Partnerships

Division Director in the Office of Quality Improvement, at [TOrloff@hrsa.gov](mailto:TOrloff@hrsa.gov) or (301) 443-3197.

**SUPPLEMENTARY INFORMATION:**

*Recipients:* Two current National Training and Technical Assistance Cooperative Agreement award recipients, as listed in Table 1.

*Amount of Non-Competitive Awards:* Two awards with a combined total of \$249,000.

*Period of Supplemental Funding:* Fiscal year 2019.

*CFDA Number:* 93.129.

*Authority:* Section 330(l) of the Public Health Service Act, as amended.

*Justification:* The award recipients will provide specialized training and technical assistance (T/TA) to health centers in geographic areas with the highest HIV burden, which include 48 counties; Washington, DC; San Juan; Puerto Rico; as well as seven states that have a substantial rural HIV burden. JSI Research and Training Institute, Inc. will provide T/TA focused on the use of data in HIV outreach, in-reach, and prevention efforts. Fenway Community

Health Center will provide T/TA focused on expanding the use of pre-exposure prophylaxis and addressing barriers to patients seeking HIV prevention care. Supplemental funds are necessary to support timely implementation of critical T/TA to health centers in geographic locations identified by the Ending the HIV Epidemic initiative. The award recipients have the demonstrated expertise and scalable experience required to swiftly address these time-sensitive T/TA needs.

TABLE 1—RECIPIENTS AND AWARD AMOUNTS

| Grant No.        | Award recipient name                           | Award amount (\$) |
|------------------|--|-------------------|
| U30CS29366 ..... | JSI Research and Training Institute, Inc ..... | 130,000           |
| U30CS22742 ..... | Fenway Community Health Center .....           | 119,000           |

Dated: July 30, 2019.

George Sigounas,  
Administrator.

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**DEPARTMENT OF HOMELAND SECURITY**

**U.S. Customs and Border Protection**

**COBRA Fees To Be Adjusted for Inflation in Fiscal Year 2020 CBP Dec. 19-08**

**AGENCY:** U.S. Customs and Border Protection, Department of Homeland Security.

**ACTION:** General notice.

**SUMMARY:** This document announces that U.S. Customs and Border Protection (CBP) is adjusting certain customs user fees and corresponding limitations established by the Consolidated Omnibus Budget Reconciliation Act (COBRA) for Fiscal Year 2020 in accordance with the Fixing America's Surface Transportation Act (FAST Act) as implemented by CBP regulations.

**DATES:** The adjusted amounts of customs COBRA user fees and their corresponding limitations set forth in this notice for Fiscal Year 2020 are required as of October 1, 2019.

**FOR FURTHER INFORMATION CONTACT:** Tina Ghiladi, Director—Office of Finance, 202-344-3722, [UserFeeNotices@cbp.dhs.gov](mailto:UserFeeNotices@cbp.dhs.gov).

**SUPPLEMENTARY INFORMATION:**

**Background**

On December 4, 2015, the Fixing America's Surface Transportation Act (FAST Act, Pub. L. 114-94) was signed into law. Section 32201 of the FAST Act amended section 13031 of the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985 (19 U.S.C. 58c) by requiring certain customs COBRA user fees and corresponding limitations to be adjusted by the Secretary of the Treasury (Secretary) to reflect certain increases in inflation.

Sections 24.22 and 24.23 of title 19 of the Code of Federal Regulations (19 CFR 24.22 and 24.23) describe the procedures that implement the requirements of the FAST Act. Specifically, paragraph (k) in section 24.22 (19 CFR 24.22(k)) sets forth the methodology to determine the change in inflation as well as the factor by which the fees and limitations will be adjusted, if necessary. The fees and limitations subject to adjustment, which are set forth in Appendix A and Appendix B of part 24, include the commercial vessel arrival fees, commercial truck arrival fees, railroad car arrival fees, private vessel arrival fees, private aircraft arrival fees, commercial aircraft and vessel passenger arrival fees, dutiable mail fees, customs broker permit user fees, barges and other bulk carriers arrival fees, and merchandise processing fees, as well as the corresponding limitations.

**Determination of Whether an Adjustment Is Necessary for Fiscal Year 2020**

In accordance with 19 CFR 24.22, CBP must determine annually whether the fees and limitations must be adjusted to

reflect inflation. For fiscal year 2020, CBP is making this determination by comparing the average of the Consumer Price Index—All Urban Consumers, U.S. All items, 1982-84 (CPI-U) for the current year (June 2018–May 2019) with the average of the CPI-U for the comparison year (June 2017–May 2018) to determine the change in inflation, if any. If there is an increase in the CPI of greater than one (1) percent, CBP must adjust the customs COBRA user fees and corresponding limitations using the methodology set forth in 19 CFR 24.22(k). Following the steps provided in paragraph (k)(2) of section 24.22, CBP has determined that the increase in the CPI between the most recent June to May 12-month period (June 2018–May 2019) and the comparison year (June 2017–May 2018) is 2.02<sup>1</sup> percent. As the increase in the CPI is greater than one (1) percent, the customs COBRA user fees and corresponding limitations must be adjusted for Fiscal Year 2020.

**Determination of the Adjusted Fees and Limitations**

Using the methodology set forth in section 24.22(k)(2) of the CBP regulations (19 CFR 24.22(k)), CBP has determined that the factor by which the base fees and limitations will be adjusted is 7.167 percent (base fees and limitations can be found in Appendix A and B to part 24 of title 19). In reaching this determination, CBP calculated the values for each variable found in

<sup>1</sup> The figures provided in this notice may be rounded for publication purposes only. The calculations for the adjusted fees and limitations were made using unrounded figures, unless otherwise noted.