

Rider Trail South, Earth City, MO 63045. (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 abbreviated application arrives at FDA's CVM. FDA records the official abbreviated 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. Department of the Treasury notifies FDA of payment. U.S. Bank and the U.S. Department of the Treasury are required to notify FDA within 1 working day, using the PIN described previously.

The tax identification number of FDA is 53-0196965.

#### *B. Application and JINAD File Submission Cover Sheet Procedures*

*Step One:* Create a user account and password. Log onto the AGDUFA website at <https://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/ucm137049.htm> and, under Application Submission Information, click on "Create AGDUFA User Fee Cover Sheet" and follow the directions. For security reasons, each firm submitting an application and/or a JINAD file submission 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 you use this site. Online instructions will walk you through this process.

*Step Two:* Create an Animal Generic Drug User Fee Cover Sheet, transmit it to FDA, and print a copy. After logging into your account with your username and password, complete the steps required to create an Animal Generic Drug User Fee Cover Sheet. One cover sheet is needed for each abbreviated application for a generic new animal drug or JINAD file submission. Once you are satisfied that the data on the cover sheet is 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 or JINAD file submission as described in section VIII.A.

*Step Four:* Submit your application or JINAD file submission.

#### *C. Product and Sponsor Fees*

By December 31, 2023, FDA will issue invoices and payment instructions for product and sponsor fees for FY 2024 using this fee schedule. Payment will be due by January 31, 2024. FDA will issue invoices in November 2024 for any products and sponsors subject to fees for FY 2024 that qualify for fees after the December 2023 billing.

Dated: October 18, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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**BILLING CODE 4164-01-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **National Institutes of Health**

#### **Center for Scientific Review; Notice of Closed Meetings**

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Cardiovascular Sciences.

*Date:* November 16, 2023.

*Time:* 10:00 a.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Margaret Chandler, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4126, MSC 7814, Bethesda, MD 20892, (301) 435-1743, [margaret.chandler@nih.gov](mailto:margaret.chandler@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics in Infection Immunology, Immune Tolerance, and Transplantation.

*Date:* November 20, 2023.

*Time:* 12:00 p.m. to 8:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Xinrui Li, Ph.D., Scientific Review Officer, Center for Scientific Review,

National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594-2084, [xinrui.li@nih.gov](mailto:xinrui.li@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics in Nephrology and Urology.

*Date:* December 7, 2023.

*Time:* 9:00 a.m. to 8:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Stacey Nicole Williams, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 867-5309, [stacey.williams@nih.gov](mailto:stacey.williams@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR: Countermeasures Against Chemical Threats Exploratory/Developmental and Full Projects.

*Date:* December 7-8, 2023.

*Time:* 10:00 a.m. to 8:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Jodie Michelle Fleming, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 812R, Bethesda, MD 20892, (301) 867-5309, [flemingjm@csr.nih.gov](mailto:flemingjm@csr.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 17, 2023.

**David W. Freeman,**

*Supervisory Program Analyst, Office of Federal Advisory Committee Policy.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Substance Abuse and Mental Health Services Administration**

#### **Agency Information Collection Activities: Proposed Collection; Comment Request**

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA