electronically, check, bank draft, or U.S. postal money order made payable to the Food and Drug Administration. 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 to you 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 *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's post office box number (P.O. Box 979033) and PIN 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. Note: In no case should the payment for the fee be submitted to FDA with the application.

When paying by wire transfer, the invoice number or PIN needs to be included. Without the invoice number or PIN, the payment may not be applied, and 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, Account Name: Food and Drug Administration, 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 FedEx, the courier must deliver the check and printed copy of the cover sheet to U.S. Bank: U.S. Bank, Attn: Government Lockbox 979033, 3180 Rider Trail S., 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 application arrives at FDA's 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. Department of the Treasury notifies FDA of receipt of an electronic or wire transfer 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 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 on ''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 you 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 your username 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.

Step Four: Submit your application.

C. Product, Establishment, and Sponsor Fees

By December 31, 2023, FDA will issue invoices and payment instructions for product, establishment, 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, establishments, 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.

[FR Doc. 2023–23373 Filed 10–20–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4468]

Animal Generic Drug User Fee Program Rates and Payment Procedures for Fiscal Year 2024

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the fee rates and payment procedures for fiscal year (FY) 2024 generic new animal drug program user fees. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Animal Generic Drug User Fee Amendments of 2023 (AGDUFA IV), authorizes FDA to collect user fees for certain abbreviated applications for generic new animal drugs, for certain generic new animal drug products, for certain sponsors of such abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs, and for certain submissions related to generic investigational new animal drug (JINAD) files. This notice establishes the fee rates for FY 2024.

DATES: The application fee rates are effective for all abbreviated applications for a generic new animal drug submitted on or after October 1, 2023, and will remain in effect through September 30, 2024. The fee rates for requests to establish a JINAD file, and for certain submissions to JINAD files established prior to October 1, 2023, are effective on October 1, 2023, and will remain in effect through September 30, 2024.

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

Medicine (CVM) at *cvmagdufa@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Section 741 of the FD&C Act (21 U.S.C. 379j–21) establishes four different types of user fees: (1) fees for certain types of abbreviated applications for generic new animal drugs; (2) annual fees for certain generic new animal drug products; (3) annual fees for certain sponsors of abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs; and (4) JINAD file fees (21 U.S.C. 379j–21(a)). When certain conditions are met, FDA will waive or reduce fees for generic new animal drugs intended solely to provide for a minor use or minor species indication (21 U.S.C. 379j–21(d)).

For FYs 2024 through FY 2028, the FD&C Act establishes a base revenue amount for each fiscal year (21 U.S.C. 379j–21(b)(1)). Base revenue amounts established for fiscal years after FY 2024 are subject to adjustment for inflation and workload. Workload increases will be adjusted for excess collections after FY 2025 (21 U.S.C. 379j–21(c)). Fees are to be established each year by FDA so that the percentage allocations for each of the fee categories is as follows: 20 percent shall be derived from fees for abbreviated applications for a generic new animal drug and JINAD file fees; 40 percent shall be derived from fees for generic new animal drug products; and 40 percent shall be derived from fees for generic new animal drug sponsors (21 U.S.C. 379j–21(b)). The target revenue amounts for each fee category for FY 2024, are as follows: for application and/or JINAD file fees, the target revenue amount is $5,000,000; for product fees, the target revenue amount is $10,000,000; and for sponsor fees, the target revenue amount is $10,000,000.

For FY 2024, the AGDUFA rates are: $126,582 for each abbreviated application for a generic new animal drug other than those subject to the criteria in section 512(d)(4) of the FD&C Act (21 U.S.C. 360b(d)(4)); $63,291 for each abbreviated application for a generic new animal drug subject to the criteria in section 512(d)(4) of the FD&C Act; $50,000 for each JINAD file request or certain submissions to established JINAD files; $16,393 for each generic new animal drug product; $258,331 for each generic new animal drug sponsor paying 100 percent of the sponsor fee; $193,748 for each generic new animal drug sponsor paying 75 percent of the sponsor fee; and $129,166 for each generic new animal drug sponsor paying 50 percent of the sponsor fee. FDA will issue invoices for FY 2024 product and sponsor fees by December 31, 2023, and payment will be due by January 31, 2024. The application fee rates are effective for all abbreviated applications for a generic new animal drug submitted on or after October 1, 2023, and will remain in effect through September 30, 2024. The fee rate for requests to establish a JINAD file, and for certain submissions to JINAD files established prior to October 1, 2023, is effective on October 1, 2023, and will remain in effect through September 30, 2024.

Applications will not be accepted for review until FDA has received full payment of application fees and any other fees owed under the AGDUFA program. Similarly, a request to establish a JINAD file will not be accepted for action by FDA until FDA has received full payment of all fees owed under the AGDUFA program. (21 U.S.C. 379j–21(e)).

II. Revenue Amount for FY 2024

A. Statutory Fee Revenue Amount

AGDUFA IV, Title III of Public Law 118–15, specifies that the aggregate base fee revenue amount for FY 2024 for all user fee categories is $25,000,000 (21 U.S.C. 379j–21(b)(1)).

B. Inflation Adjustment to Fee Revenue Amount

AGDUFA IV specifies that the annual fee revenue amount is to be adjusted for inflation increases for FY 2025 and subsequent fiscal years. (21 U.S.C. 379j–21(c)(2)). Since AGDUFA IV does not adjust for inflation until FY 2025, there is no inflation adjustment for FY 2024.

C. Workload Adjustment to Inflation Adjusted Fee Revenue Amount

The fee revenue amounts established in AGDUFA IV for FY 2025 and subsequent fiscal years are also subject to adjustment to account for changes in FDA's review workload (21 U.S.C. 379j–21(c)(3)(A)). Since AGDUFA IV does not adjust for workload until FY 2025, there is no workload adjustment for FY 2024.

D. FY 2024 Fee Revenue Amounts

AGDUFA IV specifies that the revenue amount of $25,000,000 for FY 2024 is to be divided as follows: 20 percent, or a total of $5,000,000, is to come from application and/or JINAD file fees; 40 percent, or a total of $10,000,000, is to come from product fees; and 40 percent, or a total of $10,000,000, is to come from sponsor fees (21 U.S.C. 379j–21(b)).

III. Abbreviated Application Fee and JINAD File Fee Calculations for FY 2024

A. Fee Revenues and Numbers of Fee-Paying Applications and Submissions

Each person who submits an abbreviated application for a generic new animal drug shall be subject to an application fee, with limited exceptions (21 U.S.C. 379j–21(a)(1)). The term ''abbreviated application for a generic new animal drug'' means an abbreviated application for the approval of any generic new animal drug submitted under section 512(b)(2) of the FD&C Act. FDA will also assess fees related to JINAD files. FDA will assess a fee under section 741(a)(4)(A)(i) of the FD&C Act when a person submits a request to establish a new JINAD file. FDA will assess a fee under section 741(a)(4)(A)(ii) of the FD&C Act for a person's first submission, as described below, to a JINAD file on or after October 1, 2023, where the JINAD file had been established prior to that date. The JINAD file fee is set in accordance with section 741(c)(1)(C) of the FD&C Act at $50,000. FDA will set the abbreviated application fee so that such fees combined with the JINAD file fees will generate a combined total of $5,000,000 in fee revenue for FY 2024.

To set fees for abbreviated applications for generic new animal drugs, FDA must first make some assumptions about the number of fee-paying abbreviated applications it will receive during FY 2024, the number of requests to establish new JINAD files it will receive during FY 2024, and the number of existing (prior to October 1, 2023) JINAD files to which it will receive submissions during FY 2024.

Regarding the fee for a person's first submission to an existing (prior to October 1, 2023) JINAD file on or after October 1, 2023, FDA intends to assess a fee only for the first data (or ''P'') submission to the Bioequivalence (BE) or Chemistry, Manufacturing, and Controls (CMC) technical sections of the JINAD file. The Agency has selected P submissions to the BE or CMC technical sections as the basis for assessing this fee because P submissions to these sections consistently entail the substantial use of FDA review hours during the phased review process.

The Agency knows the numbers of applications and submissions that have been submitted in previous years. Those numbers fluctuate annually. In estimating the fee revenue to be generated by application and submission fees in FY 2024, FDA is assuming that the number of applications and submissions for which

fees will be paid in FY 2024 will equal the average number of applications and submissions over the 5 most recently completed fiscal years of the AGDUFA program (FY 2018 through FY 2022).

Also, under AGDUFA IV an abbreviated application for a generic new animal drug subject to the criteria in section 512(d)(4) of the FD&C Act and submitted on or after October 1, 2013, shall be subject to 50 percent of the fee applicable to all other abbreviated applications for a generic new animal drug (21 U.S.C. 379j–21(a)(1)(C)(ii)).

The average number of original submissions of abbreviated applications for generic new animal drugs over the 5 most recently completed fiscal years is 12.6 applications not subject to the criteria in section 512(d)(4) of the FD&C Act and 6.4 submissions subject to the criteria in section 512(d)(4). Each of the submissions described under section 512(d)(4) of the FD&C Act pays 50 percent of the fee paid by the other applications and will be counted as one half of a fee. Adding all of the applications not subject to the criteria in section 512(d)(4) of the FD&C Act and 50 percent of the number that are subject to such criteria results in a total of 15.80 anticipated full fees.

Based on the previous assumptions, FDA is estimating that it will receive a total of 15.80 fee-paying generic new animal drug applications in FY 2024 (12.6 original applications paying a full fee and 6.4 applications paying a half fee).

For estimating the number of requests to establish a new JINAD file and the number of P submissions to the BE or CMC section of an existing (prior to October 1, 2023) JINAD file the Agency will receive in FY 2024, FDA took the average annual number of new JINAD file requests and P submissions to the BE or CMC section of an existing JINAD file received over the last 5 completed fiscal years. The average annual number of requests to establish new JINAD files and P submissions to the BE or CMC section of existing JINAD files over the 5 most recently completed fiscal years is 60.

Based on the previous assumptions, FDA is estimating that it will receive a total of 60 fee-paying JINAD file submissions in FY 2024 (including both requests to establish new JINAD files and first P submissions to the BE or CMC section of existing (prior to October 1, 2023) JINAD files).

B. Application Fee Rates for FY 2024

FDA must set the fee rates for FY 2024 so that the estimated 15.80 abbreviated application fees and 60 JINAD file fees will generate a total of $5,000,000. The fee for a new JINAD file request or the first submission to an existing (prior to October 1, 2023) JINAD file is $50,000 under section 741(c)(1)(C) of the FD&C Act. Therefore, the JINAD fees will generate a total of $3,000,000. Abbreviated application fees will have to generate a total of $2,000,000.

To generate this amount, the fee for a generic new animal drug application will have to be $126,582 and for those applications that are subject to the criteria set forth in section 512(d)(4) of the FD&C Act, 50 percent of that amount, or $63,291.

IV. Generic New Animal Drug Product Fee Calculations for FY 2024

A. Product Fee Revenues and Numbers of Fee-Paying Products

The generic new animal drug product fee must be paid annually by the person named as the applicant in an abbreviated application or supplemental abbreviated application for a generic new animal drug product submitted for listing under section 510 of the FD&C Act (21 U.S.C. 360), and who had an abbreviated application or supplemental abbreviated application for a generic new animal drug product pending at FDA after September 1, 2008 (see 21 U.S.C. 379j–21(a)(2)). The term ''generic new animal drug product'' means each specific strength or potency of a particular active ingredient or ingredients in final dosage form marketed by a particular manufacturer or distributor, which is uniquely identified by the labeler code and product code portions of the National Drug Code, and for which an abbreviated application for a generic new animal drug or supplemental abbreviated application for a generic new animal drug has been approved (21 U.S.C. 379j–21(k)(6)). The product fees are to be set so that they will generate $10,000,000 in fee revenue for FY 2024.

To set generic new animal drug product fees to realize $10,000,000, FDA must make some assumptions about the number of products for which these fees will be paid in FY 2024. FDA gathered data on all generic new animal drug products that have been submitted for listing under section 510 of the FD&C Act and matched this to the list of all persons who FDA estimated would have a generic new animal drug application or supplemental abbreviated application pending after September 1, 2008. As of May 2023, FDA estimates that there is a total of 616 products submitted for listing by persons who had an abbreviated application for a generic new animal drug or supplemental abbreviated application for a generic new animal drug pending after September 1, 2008. Based on this, FDA believes that a total of 616 products will be subject to this fee in FY 2024.

In estimating the fee revenue to be generated by generic new animal drug product fees in FY 2024, FDA is estimating that 1 percent of the products invoiced, or 6 products, will qualify for minor use/minor species fee waiver (see 21 U.S.C. 379j–21(d)). FDA has made this estimate at 1 percent this year, based on historical data over the past 5 completed fiscal years of the AGDUFA program.

Accordingly, the Agency estimates that a total of 610 (616 minus 6) products will be subject to product fees in FY 2024.

B. Product Fee Rates for FY 2024

FDA must set the fee rates for FY 2024 so that the estimated 610 products for which fees are paid will generate a total of $10,000,000. To generate this amount will require the fee for a generic new animal drug product, rounded to the nearest dollar, to be $16,393.

V. Generic New Animal Drug Sponsor Fee Calculations for FY 2024

A. Sponsor Fee Revenues and Numbers of Fee-Paying Sponsors

The generic new animal drug sponsor fee must be paid annually by each person who: (1) is named as the applicant in an abbreviated application for a generic new animal drug, except for an approved application for which all subject products have been removed from listing under section 510 of the FD&C Act, or has submitted an investigational submission for a generic new animal drug that has not been terminated or otherwise rendered inactive and (2) had an abbreviated application for a generic new animal drug, supplemental abbreviated application for a generic new animal drug, or investigational submission for a generic new animal drug pending at FDA after September 1, 2008 (see 21 U.S.C. 379j–21(k)(7) and 379j–21(a)(3)).

A generic new animal drug sponsor is subject to only one such fee each fiscal year (see 21 U.S.C. 379j–21(a)(3)(C)). Applicants with more than 6 approved abbreviated applications will pay 100 percent of the sponsor fee; applicants with more than 1 and fewer than 7 approved abbreviated applications will pay 75 percent of the sponsor fee; and applicants with 1 or fewer approved abbreviated applications will pay 50 percent of the sponsor fee (see 21 U.S.C. 379j–21(a)(3)(C)). The sponsor fees are to be set so that they will generate $10,000,000 in fee revenue for FY 2024.

To set generic new animal drug sponsor fees to realize $10,000,000, FDA must make some assumptions about the number of sponsors who will pay these fees in FY 2024. FDA developed data on all generic new animal drug sponsors and matched this to the list of all sponsors who had pending submissions and applications after September 1, 2008. As of May, 2023, FDA estimates that in FY 2024, 12 sponsors will pay 100 percent fees, 18 sponsors will pay 75 percent fees, and 28 sponsors will pay 50 percent fees. The total of these figures is the equivalent of 39.5 full sponsor fees (12 times 100 percent or 12, plus 18 times 75 percent or 13.5 plus 28 times 50 percent or 14).

FDA estimates that about 2 percent of all of these sponsors, or 0.79, may qualify for a minor use/minor species fee waiver (see 21 U.S.C. 379j–21(d)). FDA has made the estimate of the percentage of sponsors that will not pay fees at 2 percent this year, based on historical data over the past 5 completed fiscal years of the AGDUFA program.

Accordingly, the Agency estimates that the equivalent of 38.71 full sponsor fees (39.5 minus 0.79) are likely to be paid in FY 2024.

B. Sponsor Fee Rates for FY 2024

FDA must set the fee rates for FY 2024 so that the estimated equivalent of 38.71 full sponsor fees will generate a total of $10,000,000. To generate this amount will require the 100 percent fee for a generic new animal drug sponsor, rounded to the nearest dollar, to be $258,331. Accordingly, the fee for those paying 75 percent of the full sponsor fee will be $193,748, and the fee for those paying 50 percent of the full sponsor fee will be $129,166.

VI. Fee Schedule for FY 2024

The fee rates for FY 2024 are summarized in table 1.

TABLE 1—FY 2024 FEE RATES

User fee category	Fee rate for FY 2024
Abbreviated Application Fee for Generic New Animal Drug except those subject to the criteria in section 512(d)(4) of the FD&C Act	$126,582
Abbreviated Application Fee for Generic New Animal Drug subject to the criteria in section 512(d)(4) of the FD&C Act	63,291
JINAD File Fee	50,000
Generic New Animal Drug Product Fee	$16,393
100% Generic New Animal Drug Sponsor Fee [1]	258,331
75% Generic New Animal Drug Sponsor Fee [1]	193,748
50% Generic New Animal Drug Sponsor Fee [1]	129,166

[1] An animal drug sponsor is subject to only one fee each fiscal year.

VII. Fee Waiver or Reduction; Exemption From Fees

The types of fee waivers and reductions that applied last fiscal year still exist for FY 2024 (see 21 U.S.C. 379j–21(d)(1)). However, there is no longer an exemption for any person who submits to CVM a supplemental abbreviated application relating to a generic new animal drug approved under section 512 of the FD&C Act, solely to add the application number to the labeling of the drug in the manner specified in section 502(w)(3) of the FD&C Act (21 U.S.C. 352(w)(3)). This exemption was added in AGDUFA III, but is not a part of AGDUFA IV.

VIII. Procedures for Paying FY 2024 Fees

A. Abbreviated Application Fees, JINAD File Fees, and Payment Instructions

The FY 2024 fees established in the new fee schedule must be paid for the following applications/submissions that are subject to fees under AGDUFA IV and submitted on or after October 1, 2023: a generic new animal drug application, a submission requesting to establish a JINAD file, or the first BE or CMC submission to a JINAD file that was established prior to October 1, 2023. The payment must be made in U.S. currency from a U.S. bank by one of the following methods: wire transfer, electronically, check, bank draft, or U.S. postal money order made payable to the Food and Drug Administration. 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 to you after you submit a cover sheet. (*Note:* only full payments are accepted. No partial payments can be made online.) Once you find your invoice, select ''Pay Now'' to be redirected to *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 ''AG'', on the upper right-hand corner of your completed Animal Generic Drug User Fee Cover Sheet. Also write FDA's post office box number (P.O. Box 979033) and PIN on the enclosed check, bank draft, or money order. Mail the payment and a copy of the completed Animal Generic Drug User Fee Cover Sheet to: Food and Drug Administration, P.O. Box 979033, St. Louis, MO 63197–9000. *Note:* In no case should the payment for the fee be submitted to FDA with the application or JINAD file submission.

When paying by wire transfer, the invoice number or PIN needs to be included. Without the invoice number or PIN, the payment may not be applied, and 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, Account Name: Food and Drug Administration, 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 FedEx, the courier must deliver the check and printed copy of the cover sheet to U.S. Bank: U.S. Bank, Attn: Government Lockbox 979033, 3180

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.

[FR Doc. 2023–23374 Filed 10–20–23; 8:45 am]

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*.

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*.

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*.

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*.

(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