

INSTRUCTIONS VERIFICATION OF ANIMAL DRUG USER FEE INFORMATION

We ask that you review the current animal drug user fee information in preparation for the FY 2022 annual user fee invoices (Enclosures). You are an animal drug sponsor as defined by the Animal Drug User Fee Act (ADUFA) and you will be assessed an animal drug sponsor fee. Please review the enclosed current contact information (Enclosure A) for your organization.

We have also identified the animal drug products and establishments (Enclosure B) that would qualify you for fees based on the CVM's Drug Product Listing Database as of August 19, 2021. **The FY 2022 annual invoice will include all your products and establishments listed in the database as of October 1, 2021. Animal drug products and associated establishments added to the database after October 1, 2021 will also be assessed FY 2022 user fees and will be included in the Clean-up billing cycle.** Please review the ADUFA Organization Verification Report (Enclosure B) and note the following items:

- Add any approved product(s) not found in the enclosure that should be assessed a fee by including the NDC, Trade Name, and NADA/ANADA number for that product.
- Add any animal drug establishment(s) not found in the enclosure that should be assessed a fee by providing the CFN/FEI number, and address of the establishment. Only include those animal drug establishments that you own or operate, directly or through an affiliate, and that manufacture your products in final dosage form. Also, please correct the establishment information listed in the enclosure, if necessary.
- Delete any animal drug product(s) and establishment(s) found in the enclosure that should not be assessed user fees. Please include an explanation why the product should NOT be assessed a fee.

Animal drug products and/or establishments will not be removed from your FY2022 invoice unless the appropriate information pursuant to 21 CFR 207 has been submitted to CVM, electronically. The information must be "in our hands" dated prior to October 1, 2021 to be removed from the invoice. The invoice will include animal drug products and establishments listed in the database on or after October 1, 2021.

If you received a blank Enclosure B, it indicates CVM does not have any products listed in CVM's Drug Product Listing Database. If this is correct, return the blank Enclosure B noting that you have no approved products that should be listed pursuant to 21 CFR 207. If you have product(s) that should be listed pursuant to 21 CFR 207, please add them and follow the instructions described above.

In addition, please review the listing of New Animal Drug Applications (NADA), Abbreviated New Animal Drug Applications containing (b)(1) data (ANADA), and investigational new animal drug files (INAD) (Enclosure C) which we have identified as belonging to your organization.

Please indicate any changes in the contact name and/or address listed in Enclosure A and verify all three of the enclosures for accuracy.

Please feel free to make pen and ink changes to the enclosures and only return the enclosures that have corrections. If no corrections are needed to any of the enclosures, a simple email stating ‘no corrections needed’ will suffice. You do not need to send back the enclosures if no corrections are needed.

CONTACTS and HOW TO RETURN ENCLOSURES

If you have any general questions concerning animal drug user fees, please call or email Lisa Kable (240) 402-6888 lisa.kable@fda.hhs.gov

You must send a response to Lisa on or before September 10, 2021. Please either attach the enclosures that need corrections OR send an email stating ‘no corrections needed’. The preferred method of returning the corrected enclosures is by scanning and emailing them to lisa.kable@fda.hhs.gov.

WAIVERS – This is not a request for waivers. To avoid a delay in processing, please do **not** email/mail waivers to Lisa Kable.

You may start submitting your FY 2022 waiver request(s). These requests must be mailed separately to the CVM Waiver Officer at the following address (please note this is a **new** mailing address):

Food & Drug Administration
Center for Veterinary Medicine
MPN 2, E150
Attention: ADUFA Waiver Officer
12225 Wilkins Avenue
Rockville, MD 20852

You may also submit waiver requests electronically using eSubmitter provided you are registered with the Electronic Submission Gateway and Electronic Submission System. For more information on CVM eSubmitter, please refer to our website at <https://www.fda.gov/industry/fda-esubmitter/cvm-esubmitter-program>.

Waivers of user fees granted for previous fiscal years (i.e., FY2004 through FY 2021) are NOT valid for FY 2022; therefore, you must request a new waiver for FY 2022. FDA has developed a guidance document regarding user fees, waivers, and reductions. To reference this guidance document please refer to our website at <https://www.fda.gov/animal-veterinary/guidance-industry/user-feesaduafadufaguidances>. The guidance document will provide the necessary instructions and information that will facilitate waiver requests.