



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

August 20, 2024

Dear Colleague:

We are requesting your assistance in verifying the animal drug sponsor, product, and establishment information enclosed for your organization and corporate affiliates. Your efforts will help to ensure an accurate assessment and invoicing of annual fees for FY 2025, as authorized by the Animal Drug User Fee Amendments of 2023 (ADUFA V). We request you review the enclosures and record any appropriate updates and return them to CVM.

The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by ADUFA V, 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.

Please review the July 31, 2024, *Federal Register* notice “Animal Drug User Fee Rates and Payment Procedures for Fiscal Year 2025” that describes the FY 2025 user fee rates at [Federal Register :: Animal Drug User Fee Rates and Payment Procedures for Fiscal Year 2025](#). The invoice for the annual user fees will be issued by December 31, 2024, and payment will be due by January 31, 2025. The animal drug sponsor, product, and establishment user fees for FY 2025 are \$137,446, \$10,705, and \$157,702, respectively.

Based on FDA records your organization has been identified as an animal drug sponsor subject to an annual sponsor fee under ADUFA. We have enclosed the current contact information (Enclosure A) for your organization and a listing of the New Animal Drug Applications (NADA) and Investigational New Animal Drug files (INAD) (Enclosure C) that we have identified as belonging to your organization. Also enclosed is a listing of your approved products and establishments (Enclosure B) that also may be subject to fees according to our records. Please examine the information in the enclosures and verify its accuracy. We request that you respond as soon as possible, but no later than September 20, 2024.

We appreciate your assistance in this matter to assure our records are up to date.

Roxanne K. Schweitzer
Associate Director for Management
Center for Veterinary Medicine

Enclosures