DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

August 28, 2024

Dear Colleague:

We are requesting your assistance in verifying the generic new animal drug sponsor and product 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 Generic Drug User Fee Act of 2023 (AGDUFA IV). 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 AGDUFA IV, authorizes FDA to collect user fees for certain abbreviated applications for generic new animal drugs, generic investigational new animal drug files, generic new animal drug products, and from certain sponsors of abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs.

Please review the July 31, 2024, *Federal Register* notice "Animal Generic Drug User Fee Rates and Payment Procedures for Fiscal Year 2025" that describes the FY 2025 user fee rates at Federal Register :: Animal Generic Drug User Fee Program 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 generic new animal drug fees for FY 2025 are as follows: $270,204 for each generic new animal drug sponsor paying 100 percent of the sponsor fee; $202,653 for each generic new animal drug sponsor paying 75 percent of the sponsor fee; $135,102 for each generic new animal drug sponsor paying 50 percent of the sponsor fee; and $16,139 for each generic new animal drug product.

Based on FDA records, your organization has been identified as a generic new animal drug sponsor subject to an annual sponsor fee under AGDUFA. We have enclosed the current contact information (Enclosure A) for your organization and a listing of the Abbreviated New Animal Drug Applications (ANADA) and Generic Investigational Animal Drug files (JINAD) (Enclosure C) that we have identified as belonging to your organization. Also enclosed is a listing of your approved products (Enclosure B) that may also 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