



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

August 17, 2021

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 2022, as authorized by the Animal Generic Drug User Fee Act of 2018 (AGDUFA III). 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 III, authorizes FDA to collect user fees for certain abbreviated applications for generic new animal drugs, for certain generic new animal drug products, and for certain sponsors of such abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs.

Please review the July 23, 2021, *Federal Register* notice “Animal Generic Drug User Fee Rates and Payment Procedures for Fiscal Year 2022” that describes the FY 2022 user fee rates at <https://www.federalregister.gov/documents/2021/07/23/2021-15642/animal-generic-drug-user-fee-rates-and-payment-procedures-for-fiscal-year-2022>. The invoice for the annual user fees will be issued by December 31, 2021, and payment will be due by January 31, 2022. The generic new animal drug fees for FY2022 are as follows: \$234,297 for each generic new animal drug sponsor paying 100 percent of the sponsor fee; \$175,723 for each generic new animal drug sponsor paying 75 percent of the sponsor fee; \$117,149 for each generic new animal drug sponsor paying 50 percent of the sponsor fee; and \$17,513 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 13, 2021.

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

Sincerely,

Roxanne K.  
Schweitzer -S

Digitally signed by Roxanne K.  
Schweitzer -S  
Date: 2021.08.17 14:48:42 -0400

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

Enclosures