ENERGY & COMMERCE
CHAIR RODGERS

**MEMORANDUM**

To: Subcommittee on Health Members and Staff
From: Committee on Energy and Commerce Majority Staff
Re: Hearing entitled "Reauthorization of the Animal Drug User Fee Programs."

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On Thursday, March 30, 2023, at 9:00 a.m. in 2123 Rayburn House Office Building, the Subcommittee on Health will hold a hearing entitled, "Reauthorization of the Animal Drug User Fee Programs." The hearing will consider reauthorization of the Animal Drug User Fee Act (ADUFA) and the Animal Generic Drug User Fee Act (AGDUFA).

## I. WITNESSES

Panel I

- **Tracey Forfa**, **J.D.**, Director, Center for Veterinary Medicine (CVM), U.S. Food and Drug Administration (FDA)

Panel II

- **Rachel Cumberbatch**, **DVM**, Director, Regulatory Affairs, Animal Drugs, Animal Health Institute (AHI);
- **Stephanie Batliner**, Chair, Generic Animal Drug Alliance (GADA); and
- **Lori Teller**, **DVM**, President, American Veterinary Medical Association (AVMA)

## II. BACKGROUND

The Federal Food, Drug, and Cosmetic Act (FFDCA) provides the Food and Drug Administration (FDA) authorities to review and regulate animal drugs. Authorities over the review of brand-name (pioneer) and generic animal drugs are funded through annual discretionary appropriations and user fees paid by regulated industry. User fee revenue supplements annual Congressional appropriations to support FDA in providing greater regulatory certainty in the review of animal drug applications and in meeting commitments to performance goals, as agreed to by industry and FDA.

The FDA Center for Veterinary Medicine (CVM) is responsible for protecting both human and animal health by ensuring the safety and effectiveness of both pioneer and generic animal drugs.[1] In addition to overseeing the agency's implementation of the Animal Drug User Fee Act (ADUFA) and Animal Generic Drug User Fee Act (AGDUFA), CVM is tasked with reviewing new animal drug applications for approval, including drugs for companion animals, food-producing animals, and minor and major species, conducting post-market surveillance of animal drugs, conducting drug safety and effectiveness research and validation of analytical

[1] FDA, "About the Center for Veterinary Medicine (CVM)," https://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/default.htm.

methods for tissue residue detection, and developing guidance and policy and procedure documents for industry.

Authority to collect user fees for pioneer animal drugs was first provided for by Congress in the Animal Drug User Fee Act of 2003 (referred to as ADUFA I, P.L. 108-130) for fiscal years 2004 to 2008. Due in part to the success of the human medical user fee programs established nearly ten years earlier and concerns raised by the animal drug industry over lengthy review times and regulatory uncertainty, FDA established a user fee program whereby animal drug sponsors agree to pay user fees in exchange for FDA's commitment to meeting specified review times and negotiated performance goals. Congress granted FDA authorities over the review of generic animal drugs for FY2009 in the Animal Generic Drug User Fee Act of 2008 (AGDUFA I, P.L. 110-316). AGDUFA I was passed alongside the first reauthorization of ADUFA II, and closely models the user fee structure, programmatic goals, and 5-year sunset provisions included in the brand-name review authorities. Authorities for AGDUFA have been reauthorized three times since and will sunset September 30, 2023. For both brand-name and generic animal drug authorities, FDA may only use fee revenue for the costs of the review of applications, and not towards postmarket review activity.[2]

The process for reauthorization of both user fee programs is laid out in statute and requires FDA to develop recommendations for the upcoming reauthorization in consultation with industry stakeholders. FDA hosts meetings with scientific experts, veterinary professionals, and consumer advocacy groups to produce proposed agreements for both ADUFA and AGDUFA. FDA is directed under FDCA to transmit these agreements to Congress by January 15th of the final fiscal year of the current reauthorization.

The reauthorization documents, which were transmitted to Congress ahead of the January 15, 2023 deadline, contain commitment letters on negotiated performance goals and proposed updates to statute.[3] Notable additions to the programs are described below.

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[3] U.S. Food and Drug Administration, *Animal Drug User Fee Act Reauthorization Performance Goals and Procedures Fiscal Years 2024 through 2028* (Jan. 12, 2023) (https://www.fda.gov/media/163279/download); U.S. Food and Drug Administration, *Animal Generic Drug User Fee Act Reauthorization Performance Goals and Procedures Fiscal Years 2024 through 2028* (Jan. 12, 2023) (https://www.fda.gov/media/162252/download)

## III. ADUFA V

The proposed agreement for ADUFA V contains proposed statutory changes that address program enhancements and the financial sustainability of the program. Among other recommendations, ADUFA V would increase base funding by approximately $3 million annually for fiscal years 2024-2028, authorize up to $1 million in user fee revenue to conduct a third-party assessment of the program, reaffirm commitment to exploring additional United Kingdom and European Union Good Manufacturing mutual recognition agreements, and enhance pre-approval foreign inspection processes.

### A. Submission Review Goals

ADUFA V maintains existing review timelines of reviewing 90 percent of original and administrative New Animal Drug Applications (NADAs) within 60 days after the submission date. The agreement introduces a new review goal for Conditional Approval New Animal Drug Application (CNADAs) of reviewing 90 percent of both original and administrative CNADAs within 180 days of submission. The FDA may grant conditional approval to animal drug products intended for minor use in both minor and major species for a disease that occurs infrequently. Conditional approval allows for a period of marketing exclusivity, during which the sponsor is responsible for further demonstrating the product's safety and effectiveness.[4]

### B. Exploratory Commitments to Industry

ADUFA V contains commitments to industry to explore ways of improving the process for bringing safe and effective drugs to the market. Under the proposed agreement, FDA would agree to explore how to better utilize review pathways for Animal Drug Availability Act (ADAA) eligible combination drugs submitted as original new animal drug applications. The exploration phase would be completed by October 1, 2025, and policy and procedures regarding this pathway may be revised based on the outcomes of this examination.

FDA would also agree to explore the drug residue analytical method trial process and the feasibility of review-enhancing tools, including a "clock stop," during review of sentinel submissions. Additionally, ADUFA V contains an agreement for FDA to examine more efficient ways to provide feedback to affected parties on sponsor's animal drug development plans.

### C. Reporting Metrics

The agreement establishes reporting metrics and commitments to explore additional mechanisms for metrics. Beginning in FY 2024, ADUFA V proposes the following additional reporting metrics:

The number of certain filed/submitted sentinel submissions by review divisions; quarterly reporting in FDA-TRACK on outcomes of Investigational New Animal Drug (INAD) study

[4] FDA, "Minor Use/Minor Species," https://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/MinorUseMinorSpecies/default.htm.

submissions; the number of submissions submitted to the Office of New Animal Drug Evaluation (ONADE) by division; average review times, in hours, for protocols without data; and INAD study submissions by fiscal year.

## IV. AGDUFA IV

This would be the fourth authorization of AGDUFA, and CVM has met or exceeded nearly all performance goals in each five-year authorization period. Among other things, the proposed agreement would increase base funding by approximately $7 million and includes transparency and accountability mechanisms for Agency-Industry engagement.

### A. Submission Review Goals

AGDUFA IV would maintain existing review timelines of reviewing 90 percent of original and Abbreviated New Animal Drug Applications (ANADAs) within 240 days after the submission date and reviewing 90 percent of administrative ANADAs within 60 days after submission date. The agreement introduces a new goal of reviewing 90 percent of original submissions requesting establishment of a Generic Investigational New Animal Drug (JINAD) file, within 100 days of the submission date.

### B. Agency Transparency

The proposed agreement would establish a Bioequivalence Technical Section meeting process whereby a sponsor may request further discussion with the Agency following receipt of a response to their submission of bioequivalence study data. Additionally, AGDUFA IV would require FDA to include in its response to JINAD file submissions the Agency's current thinking regarding the Chemistry, Manufacturing, and Controls technical section as it relates to the sponsor dosage form.

## V. LEGISLATION BEING CONSIDERED

**H.R. 1418, the "Animal Drug User Fee Amendments of 2023"**

On March 7, 2023, Representatives Greg Pence (IN-06) and Kim Schrier (WA-08) introduced H.R. 1418, the Animal Drug User Fee Amendments of 2023, which would reauthorize ADUFA and AGDUFA for fiscal years 2024 to 2028.[5] Reauthorization of these programs would include the negotiated agreement on performance goals and procedures between FDA and industry for the upcoming five-year period. This would be the fifth iteration of ADUFA and the fourth iteration of AGDUFA.

[5] H.R. 1418, the Animal Drug User Fee Amendments of 2023.

**H.R. 1683, the "Generic Animal Drug Advancement Act"**

H.R. 1683, the "Generic Animal Drug Advancement Act," authored by Rep. Nancy Mace (SC-01), would amend section 512(n) of FFDCA concerning labeling requirements to allow a generic animal drug application to gain approval for fewer species than on the reference listed drug's labeling. The bill would also amend section 512(d) of FFDCA to allow new generic animal drugs to gain approval as combination products.

## VI. STAFF CONTACTS

If you have any questions regarding this hearing, please contact Clare Paoletta with Committee staff at 202-225-3641.