

ONE HUNDRED FIFTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2927
Minority (202) 225-3641

MEMORANDUM

March 12, 2018

To: Subcommittee on Health Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Hearing on “Reauthorization of Animal Drug User Fees: ADUFA and AGDUFA”

On **Wednesday, March 14th, at 10:15 a.m. in Room 2322 of the Rayburn House Office Building**, the Subcommittee will hold a legislative hearing titled “Reauthorization of Animal Drug User Fees: ADUFA and AGDUFA.” The hearing will focus on the bipartisan discussion draft which reauthorizes the Animal Drug User Fee Act (ADUFA) and the Animal Generic Drug User Fee Act (AGDUFA) for an additional five years.

I. BACKGROUND

The Animal Drug User Fee Act of 2003 (ADUFA I) authorized the Food and Drug Administration (FDA) for the first time to collect user fees from the animal drug industry to accelerate the development of animal drugs, reduce application review times, and create a more predictable, streamlined process for pioneer animal drug development and approval. In 2008, ADUFA was reauthorized for an additional five years (ADUFA II) and Congress extended FDA’s authority to collect user fees for the review of generic animal drugs through the Animal Generic Drug User Fee Act of 2008 (AGDUFA I). In 2013, ADUFA III and AGDUFA II reauthorized these programs for an additional five years and these current authorizations are set to expire on September 30, 2018.

FDA has been working since May 2016, to develop proposed recommendations to Congress for the fourth reauthorization of ADUFA and third reauthorization of AGDUFA. As part of the reauthorization process, FDA held negotiations with the regulated animal drug and generic animal drug industries and reached agreement on financial and performance recommendations for fiscal years 2019 through 2023. These recommendations were delivered to Congress in early January 2018. In February 2018 the House Energy and Commerce Committee and Senate Health, Education, Labor and Pensions (HELP) Committee jointly released a

discussion draft entitled the Animal Drug User Fee Reauthorization Act of 2018, which encompasses both agreements.

II. ADUFA IV

The discussion draft reauthorizes FDA's authority to collect fees from pioneer animal drug manufacturers at a higher level than ADUFA I-III. The total revenue generated from fees in the first year of the agreement is authorized to increase from the fiscal year (FY) 2014 amount of \$23.6 million to \$30.3 million in FY 2019. The total revenue generated from fees for the duration of the agreements is authorized to increase from \$21.6 million in FY 2015-2018 to \$29.9 million in FY 2020-2023 for a 5-year total revenue of \$150 million.

The discussion draft also clarifies that user fee dollars can be used to implement the Good Manufacturing Practice (GMP) Mutual Inspection Agreement between the United States and the European Union, with the goal of streamlining inspections of foreign facilities. The discussion draft also amends the definition of "animal drug application" in ADUFA to permit user fee funds to be used to review applications for conditional approval for minor uses or for minor species, pursuant to Section 571 of the Federal Food, Drug, and Cosmetic Act (FFDCA). The discussion draft also requires sponsors to submit all applications and other submissions electronically beginning October 1, 2018.

III. AGDUFA III

The discussion draft reauthorizes FDA's authority to collect user fees from generic animal drug manufacturers, with total revenue amounts of \$18.3 million for each FY 2019-2023. The discussion draft also restructures the collection of fee types so that 25 percent of the total revenue will come from abbreviated new animal drug application fees, 37.5 percent will come from generic new animal drug product fees, and 37 percent will come from generic new animal drug sponsor fees. The total five-year proposed revenue for AGDUFA from FY 2019-2023 is \$95 million, and \$18.3 million for FY 2019. As with pioneer animal drugs, the discussion draft would require sponsors of generic animal drugs to submit all applications and other submissions electronically beginning October 1, 2018.

IV. OTHER RELATED ISSUES

A. Antibiotic Resistance Concerns

While not specifically addressed in the discussion draft, questions concerning the overuse of antibiotics and antimicrobial resistance are often raised in the context of the reauthorization of the animal drug user fees given that the Center for Veterinary Medicine (CVM) at FDA is charged with regulating the manufacture and distribution of all drugs given to animals, including antibiotics. Antibiotic resistance is a growing public health concern and overuse of antibiotics in animals can contribute to the emergence of antimicrobial resistance that can be transferred to humans through food-producing animals and can lead to a decrease in the effectiveness of antibiotics for treating human disease.

FDA CVM has developed a multi-prong strategy to address resistance concerns arising from the use of antibiotics in food-producing animals, including through guidance on the judicious use of antimicrobials, and through data collection on antimicrobial drug sales and distribution. ADUFA II amended the FFDCA to require antimicrobial drug sponsors to annually report to FDA the amounts of antimicrobial active ingredients in their drugs sold or distributed for use in food-producing animals. The FDA is required under ADUFA II to prepare annual sales and distribution reports on information received from drug sponsors. The 2016 Summary Report released for the first time in December 2017, included species-specific estimates on the sales and distribution of antimicrobials in food-producing animals.¹ In addition, as of January 2017, medically important antimicrobials (those with importance in human medicine) are no longer able to be used in animals for production purposes and may only be used in food-producing animals under veterinary oversight.

B. Conditional Approval

Under the Minor Use and Minor Species (MUMS) Animal Health Act of 2004, a sponsor of an animal drug for a minor use or minor species can apply for “conditional approval,” which permits the availability of the drug prior to having all effectiveness data collected, but following evidence of safety and the reasonable expectation of effectiveness. If an animal drug sponsor can prove this, the product may stay on the market for up to five years while collecting ongoing effectiveness data.

In 2013 as part of ADUFA III, FDA agreed to consider conditional approvals for all animal drugs, not limited to minor uses and minor species. Following ADUFA III, FDA and the animal drug industry engaged in discussions about the feasibility of conditional approval for all animal drugs. These discussions are still ongoing. FDA has explained that there are outstanding considerations that must be addressed before the agency is able to move forward with expanding conditional approval. As FDA and industry pursue a path forward for conditional approval for all animal drugs, these issues and this topic are likely to garner continued legislative interest and consideration in the future.

V. WITNESSES

Panel I:

Steven Solomon, DVM

Director

Center for Veterinary Medicine

Food and Drug Administration

¹ Food and Drug Administration, Center for Veterinary Medicine, *2016 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals* (Dec. 2017) (<https://www.fda.gov/downloads/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/UCM588085.pdf>).

Panel II:

Richard Carnevale, VMD

Regulatory and Scientific Consultant
Animal Health Institute

Bill Zollers, PhD

Chairman
Generic Animal Drug Alliance

Michael Topper, DVM, PhD, DACVP

President
American Veterinary Medical Association