THE COMMITTEE ON ENERGY AND COMMERCE

MEMORANDUM

April 5, 2013

To: Health Subcommittee

From: Energy and Commerce Committee Majority Staff

Re: Hearing entitled "Reauthorization of Animal Drug User Fees: ADUFA and AGDUFA"

On Tuesday, April 9, 2013, at 4:00 p.m. in 2123 Rayburn House Office Building, the Subcommittee on Health will hold a hearing entitled "Reauthorization of Animal Drug User Fees: ADUFA and AGDUFA." The hearing will focus on issues surrounding the reauthorization of the Animal Drug User Fee Act (ADUFA) and Animal Generic Drug User Fee Act (AGDUFA). The following provides background on the witnesses and ADUFA/AGDUFA.

I. Witnesses

Panel I

Dr. Bernadette Dunham
Director
Center for Veterinary Medicine
Food and Drug Administration

Panel II

Dr. Richard A. Carnevale
Vice President
Regulatory, Scientific and International Affairs
Animal Health Institute

Dr. Mike Apley
Professor and Section Head
Production Medicine and Clinical Pharmacology
College of Veterinary Medicine
Kansas State University

Dr. Lance B. Price
Professor
Department of Occupational and Environmental Health
George Washington University

II. Background

ADUFA III

In 2003, Congress first enacted ADUFA to help improve the Food and Drug Administration's (FDA) review of new animal drugs. The program was modeled after the Prescription Drug User Fee Program for human drugs, and it was authorized for five years. Under the user fee authority of ADUFA I, FDA collected funds to help expedite the new animal drug approval process, reduce the application backlog and improve communications with drug sponsors. In 2008, because of the success of the program, Congress reauthorized ADUFA for five years (ADUFA II). Unless Congress reauthorizes these user fees, FDA cannot collect them after September 30, 2013.

Following the process prescribed by statute, FDA and industry negotiated an agreement regarding the size and scope of the user fees for Fiscal Years 2014-2018. In February, FDA sent its final legislative recommendations on the agreement to the Committee. Under the proposed ADUFA III agreement, the industry would pay approximately $23,600,000 in Fiscal Year 2014 ($21,600,000 plus $2,000,000 for one-time information technology funding), and similar amounts in the remaining four years based on inflation adjusters. The fee would be paid through application fees (20 percent of the total), product fees (27 percent of the total), sponsor fees (27 percent of the total), and establishment fees (26 perent of the total).[1]

AGDUFA II

In 2008, Congress authorized the AGDUFA program for five years in order to improve the review of abbreviated new animal drug applications (ANADAs). AGDUFA I enabled the agency to eliminate its application backlog and reduce review times. FDA cannot collect these user fees after September 30, 2013, unless they are reauthorized.

Similar to ADUFA, FDA and industry negotiated an agreement regarding the size and scope of AGDUFA for Fiscal Years 2014-2018, and FDA sent its final legislative recommendations on the AGDUFA agreement to the Committee in February. Under the proposed AGDUFA agreement, the industry would pay $7,328,00 in Fiscal Year 2014 ($6,478,000 plus $850,000 for one-time information technology funding), $6,944,00 in Fiscal Year 2015, $7,429,000 in Fiscal Year 2016, $7,936,000 in Fiscal Year 2017, and $8,467,000 in Fiscal Year 2018. These fees would be paid through application fees (25 percent of total), product fees (37.5 percent of total), and sponsor fees (37.5 percent of the total).[2]

[1] For more information, please see the following:
http://www.fda.gov/forindustry/userfees/animaldruguserfeeactadufa/default.htm.

[2] For additional information, please see the following:
http://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/default.htm.

III. Staff Contacts

Should you have any questions regarding this hearing, please contact Carly McWilliams or Clay Alspach at (202) 225-2927.