U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE

March 12, 2018

TO: Members, Subcommittee on Health

FROM: Committee Majority Staff

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

I. INTRODUCTION

The Subcommittee on Health will hold a hearing on Wednesday, March 14, 2018, at 10:15 a.m., in 2322 Rayburn House Office Building. The hearing is entitled "Reauthorization of Animal Drug User Fees: ADUFA and AGDUFA."

II. WITNESSES

PANEL ONE

- Steven Solomon, DVM, MPH, Director, Center for Veterinary Medicine, U.S. Food and Drug Administration.

PANEL TWO

- Rachel Cumberbatch, DVM, Director, Regulatory Affairs, Animal Drugs, Animal Health Institute;
- Bill Zollers, PhD, Chairman, Generic Animal Drug Alliance; and
- Michael Topper, DVM, PhD, DACVP, President, American Veterinary Medical Association.

III. BACKGROUND

The Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM) approves animal drugs for companion and food-producing animals; monitors the safety and effectiveness of animal drugs on the market; ensures animal food is safe, properly labeled, and produced under sanitary conditions; approves food additives; and conducts research to ensure the safety of animal drugs, food for animals, and food products made from animals. The Center's review of brand-name and generic animal drug applications is funded through a combination of annual discretionary appropriations from Congress and user fees collected from the regulated industry.

The Animal Drug User Fee Act (ADUFA) and the Animal Generic Drug User Fee Act (AGDUFA) give the FDA authority to collect user fees from sponsors of animal drugs to improve the timeliness of review of animal drug applications. Congress last reauthorized

ADUFA and AGDUFA through September 30, 2018, via the Animal Drug and Animal Generic Drug User Fee Reauthorization Act of 2013.

In February, the Committee on Energy and Commerce and the Senate Health, Education, Labor, and Pensions Committee released a bipartisan discussion draft to reauthorize ADUFA and AGDUFA.[1] Reauthorization of these programs includes the negotiated agreement on performance goals and procedures between FDA and industry for the upcoming five-year period.

This will be the fourth iteration of ADUFA, and the program has reduced review times significantly since its launch in 2004. Among other things, the proposed agreement would increase base funding by approximately $6 million annually, require that all submissions be electronic, require CVM to work toward implementation of the U.S.-EU GMP Inspection Mutual Recognition Agreement, and shorten the review time for combinations of drugs for use in feed from 180 days to 60 days when no additional data is required.

This will be the third 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 $10 million annually, shorten the review time for administrative abbreviated new animal drug applications (ANADA) from 100 days to 60 days, and require all approved drugs to include the ANADA on the labeling.

IV. STAFF CONTACTS

If you have any questions regarding this hearing, please contact Danielle Steele or Zack Dareshori of the Committee staff at (202) 225-2927.

[1] https://energycommerce.house.gov/news/press-release/house-senate-health-committee-leaders-release-discussion-draft-fda-animal-drug-user-fees-reauthorization/