Chairman Michael C. Burgess, M.D.
Opening Statement
Energy and Commerce Subcommittee on Health Hearing
"Reauthorization of Animal Drug User Fees: ADUFA and AGDUFA"
March 14, 2018

Today's hearing marks the Health Subcommittee's fourth hearing to consider the reauthorization of vital user fee programs at the U.S. Food and Drug Administration (FDA). While the bulk of these programs were reauthorized last year through the FDA Reauthorization Act of 2017, our focus today on reauthorizing the Animal Drug User Fee Act (ADUFA) and the Animal Generic Drug User Fee Act (AGDUFA) is equally important for the millions of American families and businesses that rely on the critical functions of FDA's Center for Veterinary Medicine. With this in mind, I expect us to reach a shared commitment to complete our work reauthorizing these last set of user fees and get them to the House floor well in advance of their expiration on September 30, 2018. We did it last year, so there is no reason we cannot do it again here.

This morning, we have two panels of witnesses before our subcommittee. First, I would like to welcome Dr. Steven Solomon, Director of the Center for Veterinary Medicine at FDA. Next, representatives from the Animal Health Institute, Generic Animal Drug

Alliance, and American Veterinary Medical Association will share their insights on the current state of U.S. animal drug market and the significance of reauthorizing ADUFA and AGDUFA.

Last month, the Committee on Energy and Commerce and the Senate Health, Education, Labor, and Pensions Committee released the Animal Drug User Fee Reauthorization Act of 2018, a bipartisan discussion draft to renew FDA's authority to collect user fees from the manufacturers of brand-name and generic animal drugs for another five years. Among other things, these user fees help fund FDA's Center for Veterinary Medicine's timely review of animal drug applications, market surveillance of animal drugs' safety and efficacy, and quality assurance measures for animal food as well as food products derived from animals. From pet owners and veterinarians to farmers and animal food producers, updating these user fee agreements are essential in ensuring animal drugs are safe and effective for farm animals and our pets, while keeping our food supply safe. Reauthorizing these agreements also includes the new commitments between FDA and industry on performance goals and procedures.

This will be ADUFA's fourth authorization, and since its launch in 2004, we have seen review times reduced significantly. Under the proposed agreement, funding for the program would increase by

approximately $6 million annually, all submissions must be electronic, the Center for Veterinary Medicine is required to begin implementation of the U.S.-E.U. good manufacturing practice Mutual Recognition Agreement for inspections of pharmaceutical manufacturing facilities, and review time for drug combinations for use in feed is shortened to 60 days when no additional data is required.

AGDUFA is going through its third authorization since 2008. The Center for Veterinary Medicine has met or exceeded nearly all performance goals in each five-year authorization period. In addition to increasing funding by approximately $10 million annually, the proposed agreement would shorten the review time for abbreviated new animal drug applications to 60 days and require all approved drugs to include these applications on the labeling.

Finally, I would like to commend our fellow Health Subcommittee member, Representative Mullin, for championing the House ADUFA/AGDUFA Reauthorization bill. Thank you for all your hard work on this important measure.

I again want to welcome all of our witnesses and thank you for being here. I look forward to your testimony.

I yield the balance of my time to Ms. Blackburn of Tennessee, for a statement.