Brett Guthrie
Health Subcommittee Hearing
March 30, 2023
Opening Statement
As Prepared for Delivery

Today we take the first step to reauthorizing the Animal Drug User Fee Agreements for years 2024-2028. This process gives Congress the unique ability to help ensure pioneer drugs – or brand name animal drugs – and their generic equivalents are able to reach the market as quickly and as safely as possible. These must pass agreements ensure that our best four-legged friends to our farm animals are healthy and happy. Animal health is also important to human health. For example, there's currently a severe bird flu outbreak going on around the world. One way to prevent that virus from potentially mutating and becoming potentially infectious in humans is to prevent or cure the disease in animals.

Originally established in 2004, the first animal drug user fee agreement transformed the new animal drug application review process. Before the establishment of these agreements, it took roughly 7 to 10 years to get new animal drugs approved and about an average of $100 million dollars of investment. This backlog made it more difficult for veterinarians to treat house pets for treatable and non-life threatening conditions. It also made it more difficult to determine that drugs given to food producing animals did not jeopardize the safety of that food for human consumption, and delayed the process of getting these critical foods onto grocery shelves.

The first ADUFA agreement decreased the review times for New Animal Drug Applications from over 600 days to 180 days and eliminated the backlog of applications sitting with the FDA Center for Veterinary Medicine. The agreement for our consideration today will allow the agency to collect $174 million in fees from industry through from 2024 to 2028, while making critical program enhancements designed to streamline the review process for both the regulators and industry. These include more stringent reporting requirements for the FDA related to review times and outcomes of Investigational New Animal Drug applications in addition to a third party review process for more oversight over the review process of these applications to help identify ways in which this process can be more predictable for animal drug sponsors.

Today we are also considering the Animal Generic Drug User Fee Agreements (AGDUFA), which would permit the FDA to collect up to $130 million in user fees through 2028. These agreements have been instrumental in getting more lower cost drugs onto the market since Congress first passed AGDUFA in 2009, which was helpful in reducing long wait times for drug reviews and getting decisions on the 450 applications sitting with the Center for Veterinary Medicine for review in 2007.

The AGDUFA before us today includes improved transparency requirements for FDA that will help sponsors more effectively work with regulators to address outstanding issues with the file sponsors use to share information about abbreviated new animal drug applications. It also includes a commitment from the FDA to take action on 90% of these requests within 100 days of submission.

Overall, both of these agreements will significantly enhance our ability to keep our animals, both household pets and farming animals, healthy, while continuing to promote human health in the process.

I would also like to thank my subcommittee colleagues Representatives Pence and Schrier for their work in introducing the legislation before us today that would reauthorize both the animal drug user fee program and the generic animal drug user fee program at the FDA through 2028. As subcommittee chair, it is a top priority for me to ensure we get this legislation to the President's desk well before its September 30 deadline.

Thank you, and I yield back.