Committee on Energy and Commerce

Opening Statement as Prepared for Delivery
of
Subcommittee on Health Ranking Member Anna Eshoo

***Hearing on* "Reauthorization of the Animal Drug User Fee Programs."**

March 30, 2023

Today we consider the reauthorization of the animal drug user fee programs. A source of pride of this Subcommittee is our history of bipartisan work to advance user fee agreements that enable the U.S. to lead the world in innovation and drug development.

I voted for the initial Animal Drug User Fee Act known as ADUFA in 2003 to authorize the FDA to collect fees for animal drug applications, as well as the Animal Generic Drug User Fee Act known as AGDUFA in 2008 to expand these authorities to generic animal drugs.

These programs are reauthorized every five years to ensure the Center for Veterinary Medicine can continue to meet the needs of the animal drug industry as it evolves.

Today we're considering a new set of agreements negotiated by the FDA and stakeholders in the animal drug industry. These agreements will lead to increased transparency, additional pathways for animal drug approvals, and reduced review times for pioneer and generic drug applications while maintaining high standards for safety and efficacy.

Everyone on this Subcommittee has a vested interest in moving these reauthorizations because they are critical to animal and human health. Millions of American pet owners and veterinarians rely on the robust animal drug pipeline to keep their companions safe and healthy.

Livestock and poultry producers also rely on animal health products to protect food-producing animals from diseases that threaten the safety of the food supply.

FDA continues to make progress to mitigate the growth of antimicrobial resistance in food-producing animals, including ending over-the-counter access to medically-important antibiotics which are used in both humans and animals, but more needs to be done.

ADUFA V and AGDUFA IV are the latest evolutions to further strengthen the review process for animal drugs and ensure robust funding for the Center for Veterinary Medicine.

We're also considering Congresswoman Nancy Mace's legislation, the *Generic Animal Drug Advancement Act* to allow a generic animal drug manufacturer to seek approval for fewer species than were on the original pioneer drug's labeling.

Thank you, Director Forfa, for being with us today. I look forward to hearing from you and our other expert witnesses about the negotiated animal user fee agreements.

I remain fully committed to moving ADUFA and AGDUFA through a swift reauthorization before the programs expire on September 30th.