Congresswoman Cathy McMorris Rodgers
Health Subcommittee Hearing
March 30, 2023
Opening Statement
As Prepared for Delivery

INTRO

Good morning.

Whether or not you know it, almost everyone in this room relies on the animal drugs approved by the FDA.

Whether you have a pet, drink milk, or eat meat, the FDA plays a very important role in making sure the drugs we give animals work and are safe.

This is particularly important to make sure food is safe for humans to eat.

The Center for Veterinary Medicine at FDA is responsible for regulating animal drugs and is funded in part by Congressional appropriations and in part by user fees paid by industry.

If we don't reauthorize this legislation on time, FDA can no longer collect fees and the drugs that farmers and pet owners rely on may not come to market.

It is important we get this done on time and work in a bipartisan way to keep any controversial policies from slowing this down.

We're off to good start.

I am glad that industry and FDA submitted recommendations for this reauthorization ahead of the January 15th deadline, and that today we will be considering legislation that the reauthorizes the Animal Drug User Fee Amendments and the Animal Generic Drug User Fee Amendments.

The agreements before us reflect nearly two years of negotiations between FDA and industry…and we appreciate the hard work from those involved in those discussions.

Proposed Agreements

This will be the fifth ADUFA reauthorization and the fourth reauthorization of AGDUFA…

…and in the twenty years since these authorities were established, we've seen significant improvements to review times for new animal drug applications and continued progress towards getting safe and cost-effective products to the market faster.

Over the course of the negotiation process, we have heard from industry and stakeholders on current challenges within the animal health market, including rising costs of pet care and limited options available for treatment.

We are also hearing how the significant growth in new drug application fees are limiting participation in the animal drug user fee programs. This ultimately leaves us with fewer and less affordable options to treat our country's animals.

It is clear that we need more innovative and affordable medicines on the market and I look forward to discussing FDA's plans to better utilize existing processes to expedite the review and approval of animal drugs.

The agreements contain several proposals that address supply chain issues, funding for pre-approval foreign inspections capabilities, and commitments to exploring additional EU and US Good Manufacturing agreements.

FDA will also commit to a third-party evaluation of CVM's utilization of review processes for animal drug applications.

Independent assessments such as these are critical as this Committee conducts oversight over the Agency's mission in fulfilling its regulatory and public health responsibilities.

We look forward to reviewing the findings from this assessment.

The proposed agreement for the Animal Generic Drug User Fee Program should help get more lower cost animal drugs to farmers and pet owners.

FDA has committed to providing increased engagement with generic drug sponsors through new meeting processes.

These meetings will provide additional opportunities for sponsors to engage with the Agency's scientific staff to better understand what data is needed to support their new animal drug applications.

I also look forward to discussing CVM's plans to transition staff and resources back to in-person operations as we turn the corner on three years since the beginning of the pandemic and as the COVID-19 public health emergency is set to end on May 11.

In addition to the user fee agreements, we are also considering legislation introduced by Representative Nancy Mace, the "Generic Animal Drug Availability Act."

This bill would improve pathways for generic animal drugs seeking approval for single species and as combination products.

CONCLUSION

I look forward to today's discussion. I believe there is a bipartisan commitment to reauthorizing these agreements on time.

Thank you and I yield back.