Summary of the American Veterinary Medical Association (AVMA) Written Testimony for the "Reauthorization of the Animal Drug User Fee Programs"

Hearing Date: March 30, 2023

- The AVMA is the largest veterinary organization in the United States with over 101,000 members, who care passionately about protecting animal health, animal welfare, and human health. Informed by our members' unique scientific knowledge and clinical training, the AVMA advocates for policies that advance the science and practice of veterinary medicine and furthers the critical work of veterinarians nationwide.
- The AVMA supports the collection and effective utilization of user fees to enhance the FDA Center for Veterinary Medicine's (FDA CVM) review of pioneer and generic animal drugs. Veterinarians treat many species across a range of sizes for a variety of diseases and conditions. Despite this vast range of needs, veterinarians have far fewer FDA-approved animal drugs compared to the number of FDA-approved human drugs. Veterinarians need more new pioneer and generic animal drugs demonstrated to be safe and effective, as well as reasonably priced.
- The AVMA recommends FDA CVM consider adopting processes used by other similar regulatory agencies to streamline and shorten the animal drug review process, prioritize applications for which another generic animal drug is not available, while continuing to approve more generic animal drugs to provide market stability.
- Veterinarians need a robust pipeline of innovative new animal drugs and a strong generic industry to provide the best care for our patients.

United States House of Representatives

Committee on Energy and Commerce

Subcommittee on Health

Hearing

"Reauthorization of Animal Drug User Fees 2023:

ADUFA and AGDUFA"

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Testimony of

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Introduction

Thank you, and good morning, Chairman Guthrie, Ranking Member Eshoo, and Members of the Subcommittee. I am Dr. Lori Teller, President of the American Veterinary Medical Association. On behalf of the AVMA, I appreciate the opportunity to emphasize the importance of reauthorizing the Animal Drug User Fee Act (ADUFA) and the Animal Generic Drug User Fee Act (AGDUFA) for our veterinarian members.

Since its founding in 1863, the AVMA has grown to be the largest veterinary organization in the United States with over 101,000 members who care passionately about protecting animal health, animal welfare, and human health. Our veterinarian members serve society across the spectrum of the profession, including private clinical practice, public health, biomedical research, academia, food safety, biosecurity, biodefense, and more. Informed by our members' unique scientific knowledge and clinical training, the AVMA advocates for policies that advance the science and practice of veterinary medicine and furthers the critical work of veterinarians nationwide.

Background and Support

The AVMA supports the collection and effective utilization of user fees to enhance the U.S. Food and Drug Administration Center for Veterinary Medicine's (FDA CVM) review of pioneer and generic animal drugs. The intent of these user fee programs is to provide sponsors with a predictable pathway to market for new and innovative animal drugs. Veterinarians need more new and innovative animal drugs demonstrated to be safe and effective. Access to new FDA-approved animal drugs has the potential to improve treatment outcomes, provide better alternatives to existing therapies, fill unmet medical needs in veterinary medicine, and ultimately improve patient care.

The needs of veterinarians are unique because we treat a multitude of species across an incredible range of sizes for a variety of diseases and conditions. Despite this vast range of needs, veterinarians have far fewer FDA-approved animal drugs available than our colleagues who treat human patients. In addition, the metabolic pathway among species differs, so a drug used to treat dogs does not act exactly the same way in cats, nor in horses, cattle, turkeys, honeybees, lemurs, or any other animal species. These inherent pharmacokinetic and pharmacodynamic differences among species serve as very real hurdles in the treatment of our patients because so few treatment options exist. Also, for food-producing species, our veterinarians take care to ensure food derived from these animals does not contain violative drug residues and is safe for human consumption. Our medical education, clinical training, and understanding of the pharmaceutical products we use, allow us to navigate these challenging waters. However, the lack of approved animal drugs limits treatment options for our patients. More innovative approved animal drugs are needed for optimal patient care and the protection of public health.

Effective utilization of user fees under ADUFA and AGDUFA is of keen interest to veterinarians, as we are the primary prescribers and purchasers of FDA-approved animal drugs. Ultimately, however, it is our clients who pay the cost of FDA-approved animal drugs. Drug costs directly impact our clients' ability to care for their animals. Animal owners thereby rely on animal drugs to not only be safe and effective but also reasonably priced. We urge FDA CVM to ensure the review and approval process is efficient in bringing new animal drugs to market to safeguard the public's access to affordable treatment for their animals.

Recommendations

Under previous animal drug user fee agreements, FDA CVM committed to utilizing user fees to improve the efficiency of the animal drug review process; however, we believe additional work is needed to attain the programs' goals of more and expedited animal drug approvals. First, the AVMA suggests, where appropriate, that FDA CVM consider adopting processes used by other similar regulatory agencies that may streamline and shorten the time needed to approve animal drugs for the US market. We believe there should be alignment between the US drug approval process and approval processes used in other developed countries with respect to the timeliness of reviews. When reviewing the same data, our understanding is US approvals lag behind Europe and Canada by up to a year. The US is the largest animal drug market in the world and should be the leader in bringing innovative products to market.

With respect to the AGDUFA program, veterinarians need access to more generic animal drugs that have been demonstrated to be bioequivalent to pioneer drugs, are properly manufactured, accurately labeled, are subject to post-market approval requirements, and are available at a reasonable cost. We need generic drugs for new areas where there is currently no generic competition, and having multiple generic approvals for a pioneer drug provides stability in the market.

We recommend FDA CVM prioritize those applications for which a generic animal drug is not currently available. Having multiple generic approvals for the same product, while good, does not carry the same impact as the first new generic drug approval when a pioneer drug comes off patent or an exclusivity period expires. The approval of more generic animal drugs also would signal to manufacturers that their time and investment in generic drugs is worthwhile leading to increased competition and ultimately reduced

costs borne by our clients.

However, having multiple generic animal drug approvals for the same pioneer drug can be beneficial. The supply chain volatility and vulnerability experienced over the past several years have demonstrated the need for multiple sources of important animal drugs. More approvals of generic animal drugs help ensure consistent access to the drugs veterinarians need to treat our patients. In such instances, access to another FDA-approved generic animal drug with demonstrated bioequivalence that is manufactured under FDA's good manufacturing practices is preferred to alternatives such as compounded drugs.

Conclusion

Ultimately, in order to provide the best care, we need a robust pipeline of innovative new animal drugs and a strong generic industry. Thank you for the opportunity to provide testimony on these important programs. The AVMA appreciates the attention the Subcommittee is giving to this issue and its commitment to addressing unmet needs in veterinary medicine. We look forward to working with the Committee and FDA CVM to increase the number of approved animal drugs for the benefit of the animals under our care, their owners, and the public. Thank you again, and I am happy to answer any questions.