Testimony of

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Committee on Energy & Commerce
Subcommittee on Health

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Chairman Guthrie, Ranking Member Eshoo, and members of the Subcommittee, on behalf of the Generic Animal Drug Alliance (GADA), thank you for the opportunity to testify today. GADA supports the re-authorization of the user fee program and more specifically supports the Animal Generic Drug User Fee Act of 2023 (AGDUFA IV). GADA has previously provided testimony to this Subcommittee in support of AGDUFA I, II and most recently in 2018 for AGDUFA III. GADA is the only U.S. based independent professional trade organization that represents the interests of generic animal drug sponsors and industry stakeholders such as manufacturers, distributors, suppliers and service providers. Our members' products and processes are regulated by the Food and Drug Administration's Center for Veterinary Medicine (FDA-CVM). Our members are focused on the development, regulatory approval and marketing of high quality generic drugs for livestock and pets and to advocate for policies that support the continued availability and affordability of pharmaceutical treatments for animals.

Generic animal drugs provide significant benefits to the public by providing cost-effective alternatives to their pioneer drug counterparts, and by providing supply security and access to pharmaceutical treatments that would otherwise be unavailable to the veterinary health community. Lower cost generic animal drug options help contribute to the safety of the nation's food supply, the treatment of diseases in animals that can be transmitted to humans, and the ability of owners to provide care to their pet family members. Generic animal drugs also support continuity of supply for a range of products that would otherwise be unavailable due to supply chain issues or discontinuation of pioneer products. However, the potential cost savings and supply advantages to farmers and pet owners from use of generic animal drugs

cannot be fully achieved without broad availability. Therefore, it is critical that the FDA-CVM regulatory review and approval process for generic animal drugs is both efficient and predictable.

GADA supports the passage of the AGDUFA IV program as negotiated and presented before the Subcommittee today. Over its history, the AGDUFA program has made significant strides in addressing some of the fundamental issues around regulatory review and approval of generic animal drugs. Interest in development of generic animal drugs remains strong, and FDA-CVM reports significant review workload increases. Sponsor numbers have seen a small decline, and the number of fee-paying applications (generic animal drug approvals) has remained essentially stable.

As shared with FDA-CVM during the negotiations for the AGDUFA IV program, the following GADA objectives have been and remain at the forefront:

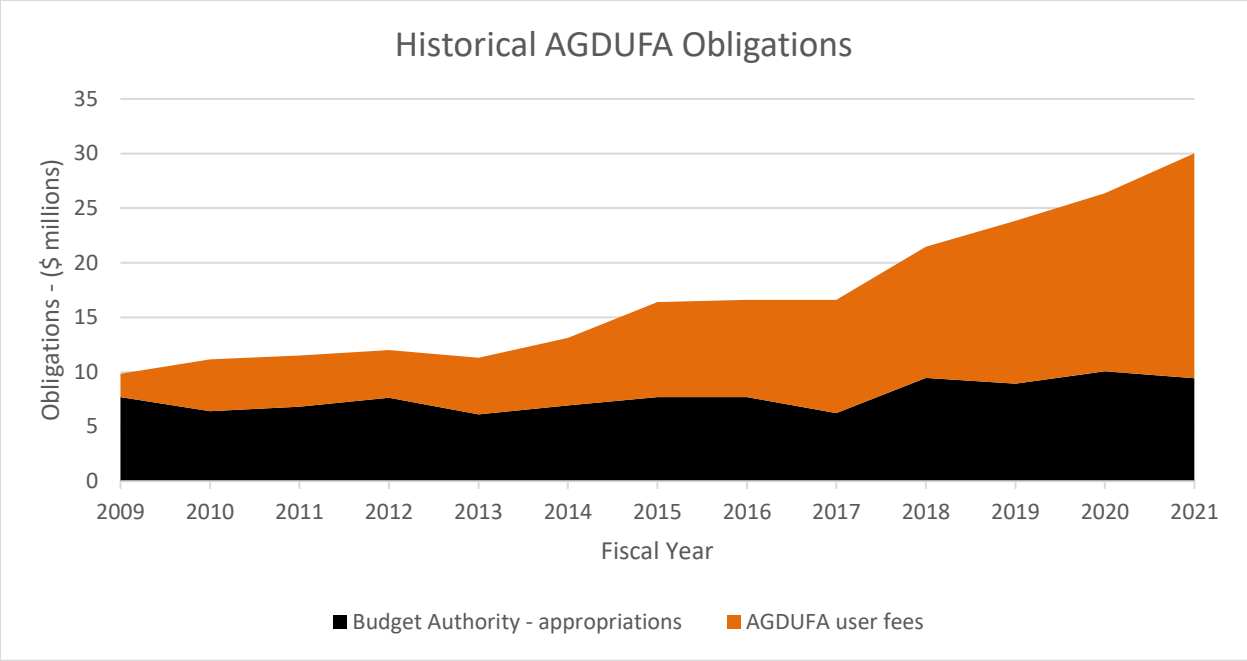
> GADA is committed to collaborating with FDA-CVM to implement enhancements to a functional user fee program that supports an efficient FDA review and a predictable and timely approval process that fosters public health by increasing the availability of high quality, safe and effective, low-cost, FDA-approved generic animal drugs.
>
> The AGDUFA user fee program must employ a cost-effective and equitable payment structure to support a highly competitive marketplace for generic animal drug companies small and large.

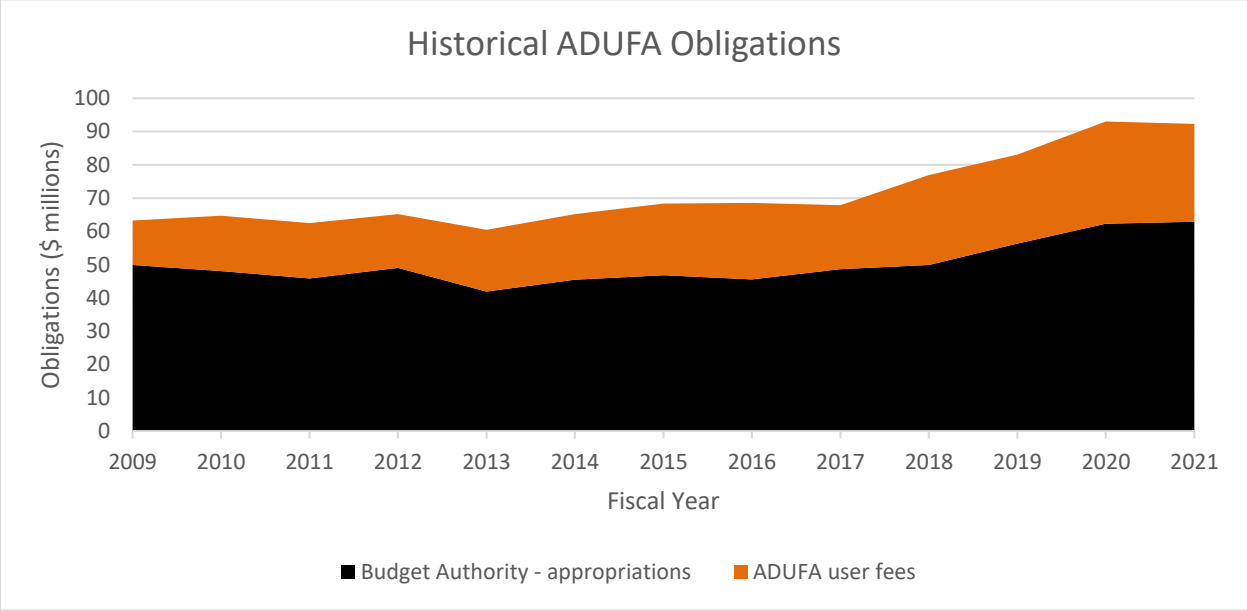
While the proposed AGDUFA IV program does not include significant review program

enhancements (such as reduced review timelines or increased metrics around efficiency of the program) we heartily support the enhancements proposed for AGDUFA IV. The program will course-correct the calculation of the workload adjuster and incorporate a fee for initiation of an investigational file. We remain committed to our tiered approach to the sponsor fee and support the increased percentage contribution of the sponsor and product fees, in an effort to shift more fees to those sponsors with actively marketed generic animal drugs.

The user fee program is not perfect, however. While the predictability and duration of FDA-CVM review timelines have incentivized sponsors to invest in the development of generic animal drugs, the user fees required to participate in this industry have escalated significantly. Recognizing the relatively small market potential of a generic animal drug, GADA is concerned that as user fees continue to escalate, sponsors may choose only to pursue the most lucrative products, leaving the public with fewer drug options, and underserved animal health needs.

It is impossible to review the animal drug review programs to date without noticing the disparity between how the generic and pioneer animal drug programs are funded. The ratio of Congressional Budget Authority to user fee funding between the two review programs is radically different. On the generic animal drug side, the industry funds roughly two-thirds of the total FDA-CVM review program cost through user fees, whereas the pioneer animal drug industry funds roughly one-third of that review program cost through user fees.





Significant growth in generic animal drug user fees resulted in a generic application fee that is near half a million dollars in the AGDUFA III program. The application fee has increased to the point that it becomes a deciding factor in which products generic sponsors are willing to

pursue. The increases in the generic animal drug application fees have far outpaced that of any other user fee program for regulated industry. We acknowledge that FDA-CVM proposed additional monies for the generic animal drug review program in the President's FY2023 budget; however, more budget authority funding will be needed to close the gap between the two programs and ensure a competitive market for cost-saving generic animal drugs. GADA welcomes the opportunity to work with the relevant congressional committees to appropriately fund the FDA-CVM review program for generic animal drugs.

Each of the AGDUFA programs to date have reported significant growth in FDA-CVM review workload. While that should be good news for the generic animal drug industry, there appears to be a disconnect. More workload has not resulted in proportionally more generic animal drug approvals. Despite the millions invested in the FDA-CVM review program, and each AGDUFA program's annual Performance Report to Congress claiming significant process enhancements and efficiencies, industry is not experiencing a streamlined, efficient review program. In 2021, generic animal drug sponsors overall made nearly twice as many submissions than in 2017, however the number of generic animal drug approvals per year has remained relatively stable. Therefore, there is a desire for more visibility and accountability, in the form of measurable, objective metrics to monitor the health and efficiency of the FDA-CVM generic animal drug review program. On the whole the proposed AGDUFA IV program does make progress in addressing some of industry's fundamental concerns, however the disparity between Congressional budget authority funding levels between pioneer and generic animal drug review programs remains.

For this fourth reauthorization of AGDUFA, the focus should remain on ensuring the program is cost-effective, efficient, predictable and geared toward expediting the availability of FDA approved generic animal drugs based on sound science. The program should be sustainable and acknowledge the realities of the generic animal drug market in the United States. The industry is comprised of many small companies with significantly smaller product markets than those for human generic drugs. CVM should have the resources necessary to meet the stated goals of AGDUFA, and to protect the generic animal drug industry from unfair competition from illegal pharmacy compounding. The source of those resources must shift toward a more equitable funding of the program from Congressional appropriations. Industry does not support the use of user fee funds for surveillance and enforcement activities.

Generic animal drug sponsors are incredibly diverse with both large and very small sponsor companies, and it should be noted that there is significant overlap between the ADUFA (Animal Drug User Fee Act) pioneer drug program & AGDUFA: many generic animal drug sponsors pay fees into both programs. As a generic industry there is a distinct focus on economics; there is truly a limit to the level of user fee funding industry can bear before it becomes a barrier to investment in generics. Therefore, it is vital that Congressional appropriations should be proportionally increased and continue to be provided to the Center of Veterinary Medicine to significantly support the review of generic animal drug applications.

While generic animal drugs are in the spotlight, we also support and call for the passage of the Generic Animal Drug Advancement Act, H.R. 1683, introduced by Rep. Nancy Mace. This legislation adjusts decades old legislative language that have left generic animal drug sponsors

at a significant disadvantage. The legislative fixes would update FDA animal drug labeling requirements to allow generic animal drugs sponsors to gain approval for a single species, rather than all species labeled on a pioneer animal drug product, as well as expand pathways for generic animal drug products to be approved as combination products. We thank the Committee for including H.R. 1683 in today's discussion.

In conclusion, GADA supports the proposed legislation for the timely re-authorization of AGDUFA IV. It remains critical for the continued viability of the veterinary generic drug industry that the FDA-CVM review process maintains predictability and improves efficiency. Reauthorization of AGDUFA is critical to continuing to make the pursuit of generic animal drug approvals viable and to increase the number of safe and effective generic animal drug products on the market. Additionally, Congressional appropriations must continue at an increased level to ensure that FDA-CVM is able to meet its public health mission and the important public policy goal of providing generic animal drug options for farmers and pet owners.

Thank you for the opportunity to share the views of the Generic Animal Drug Alliance and I welcome answering any questions you may have.