March 14, 2018
US House of Representatives
Committee on Energy and Commerce
Subcommittee on Health

Dear Honorable Members:

The Generic Animal Drug Alliance (GADA) is providing testimony to the Subcommittee on Health of the Committee on Energy and Commerce in support of the re-authorization of the Animal Generic Drug User Fee Act of 2018 (AGDUFA). The GADA has previously provided testimony to this Subcommittee in support of AGDUFA I in 2008 and AGDUFA II in 2013. The GADA is an independent professional trade organization that represents the interests of generic animal drug companies. We are the only trade organization that represents the interests of sponsors, manufacturers, distributors, suppliers and service providers of generic animal drugs. Our products and processes are regulated by the Food and Drug Administration, 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.

Just like with human generic drugs, generic animal drugs provide significant benefits to the public by providing cost-effective alternatives to their pioneer drug counterparts. 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. However, the potential cost savings to famers

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

AGDUFA was a successful first step in achieving these goals. Prior to the implementation of AGDUFA I, a single CVM review cycle of a generic application could take longer than two years. In most cases, multiple review cycles are needed, so if an application required three review cycles, it could take more than six to eight years to receive approval. In the time it took to get an application approved, the entire market for a generic drug could change, making it no longer cost-effective to market. This created a disincentive for companies to pursue generic animal drug approvals and denied the public cost-effective veterinary generic drugs. The industry remembers this time in our history. No one involved in the approval process for generic drugs wants to see these conditions return. Therefore, the industry is stepping up again to support the reauthorization of AGDUFA.

Since AGDUFA began, CVM has reduced the review time of an application to a more predictable 270 days. In addition, CVM implemented several process enhancements and increased communications with industry. We believe the shorter more predictable review times are helping contribute to the growth of our industry. As part of the current reauthorization of AGDUFA III, the industry has agreed to significantly increase our financial contributions so that the generic industry could receive even shorter review periods that are equivalent to those experienced by the sponsors of pioneer drugs. As currently written, AGDUFA III will further shorten some critical submission review cycle times from 270 days to 180 days.

The industry is comprised of many small companies and product markets that are much smaller than those for human generic drugs. Therefore, it is vital that Congressional appropriations continue to be provided to the Center of Veterinary Medicine to significantly support the review of generic drug applications. For this to be achieved, appropriations must continue at an increased level that enables CVM to meet its public health mission and the important public policy goal of providing generic drug options for farmers and pet owners.

We believe AGDUFA III provides the review time targets that industry requires to counterbalance the financial investment being made in support of CVM's needed resources to build capacity and balance the realities of a small but growing generics industry. In addition, the proposed AGDUFA III enhancement concerning e-Submissions should make the approval process more efficient. Also, the proposed revisions to the overcollections and offset provisions will more immediately reduce the financial burden if overpayments are made by the industry. This will also make funding more efficiently ready for use by CVM to continue to improve the generic drug review process. Overall, we are hopeful that the reduction in review times will lead to a shortened time from project initiation to approval allowing generic products to come to market sooner.

In conclusion, the GADA supports the proposed legislation for re-authorization of AGDUFA. Without timely reauthorization, we will return to the untenable situation pre-AGDUFA when lengthy application reviews served as a disincentive to companies pursuing generic animal drugs. It remains critical for the continued viability of the veterinary generic drug industry that

the FDA/CVM review process maintains and improves predictability and 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 drugs on the market.

Sincerely,

The Generic Animal Drug Alliance