GADA

GENERIC ANIMAL DRUG ALLIANCE

June 4, 2008

U.S. 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 Animal Generic Drug User Fee Act of 2008 (AGDUFA) and the Animal Drug User Fee Act Amendments of 2008 (ADUFA). The GADA is an independent professional trade organization that represents the interests of generic animal health companies before Federal regulatory agencies and Congress. We are the only trade organization that represents the interests of sponsors, manufacturers and distributors of generic drugs in the animal health industry. Our products and processes are regulated by the Food and Drug Administration, Center for Veterinary Medicine (FDA/CVM) We have been assured by FDA/CVM that our organization represents a solid majority of firms so engaged in generic animal drugs.

It is critical to the success of the animal health generic drug industry to have a predictable and efficient FDA/CVM review process for approval of abbreviated new animal drugs (ANADAs). As in the human generic market, generic animal drugs account for a high volume of units sold at dramatically lower prices than pioneer products. Generic animal drugs are essential to both pet owners and food producers to reduce costs and increase accessibility of therapeutic pharmaceuticals. Through access to and affordability of therapeutic pharmaceuticals, the generic animal health industry aids in the protection of our nation's food supply and the safety of pet owners. The current review process is an untenable situation both for the generic drug industry and FDA/CVM. The statutory timeframe for review of an ANADA is 180 days. The initial review cycles for ANADAs today are approaching 600 days – far beyond reasonable and practical review times, and more than one review cycle is now routinely required before an ANADA is approved. Therefore, from filing an ANADA to ultimate approval is now in the range of 4 to 5 years. For this reason, GADA believes the generic review process is at a critical juncture. Despite efforts on behalf of industry and FDA/CVM to resolve this issue without the implementation of a user fee act, the appropriations shortfall for dedicated generic application resources is currently insurmountable without funding from an additional source.

Our support for AGDUFA arises from our collective experience that ADUFA 2003 performance goals were consistently met by FDA/CVM, resulting in shortened regulatory review cycle timeframes. The FDA/CVM is the regulatory agency that oversees the pioneer and generic animal drug approval process. As should be expected by U.S. citizens, the approval of all animal drugs requires a thorough and rigorous, science-based process. A sponsor must demonstrate that their drug is safe and effective for the animal, the environment and for humans consuming the

food from treated animals and meets quality manufacturing standards and practices. Therefore, building from the success of ADUFA 2003, GADA and FDA/CVM entered into negotiations to establish a similar user fee program (AGDUFA) for ANADAs. The member companies of GADA worked with FDA/CVM to establish appropriate parameters for a user fee program that allows a more predictable and efficient review process. We were able to define the boundaries necessitated by the economics of the generic animal drug industry and still arrive at an outcome that ensures a stable, reliable revenue source to support the review process at FDA/CVM in a manner not currently met by appropriated funds. The shortened review cycles that will result from the agreed upon performance goals will provide predictability and practicality and encourage further investment in research and development for generic animal drugs.

The legislative language and associated performance goals contained within the proposal for AGDUFA are very similar to that enacted in ADUFA 2003. We were able to utilize the framework already in place within FDA/CVM for the administration of the user fee program and learn from previous experiences. There are, however, several important differences between AGDUFA and ADUFA 2003: 1) AGDUFA participants will not pay an establishment fee, 2) the sponsor fee prescribed within AGDUFA is tiered to provide relief to sponsors who hold fewer ANADA approvals, 3) the performance goals for AGDUFA do not return generic application review times to statutory requirements, (180 days), rather 270 days is the highest level of performance that the generic animal drug industry can afford. While we are pleased with the overall content of the legislative proposal, additional funding requirements for FDA/CVM became apparent during our negotiations.

The success of AGDUFA will help maintain a competitive and thriving generic animal drug industry. Ultimately, this will provide alternatives for the end-user that will help contain cost while maintaining safety of the U.S. food supply and pet owners. We would emphasize that AGDUFA does not reduce the robust requirements in place for approval of a generic animal drug. The purpose of AGDUFA is to supplement resources used specifically for review of applications and administration of the regulatory process - not to alter the existing stringent requirements for approval of a generic animal drug. All pre-approval animal safety, efficacy and human food safety requirements remain the same. In fact, we could argue that AGDUFA will allow for more comprehensive reviews of generic animal drug applications by providing the resources necessary for FDA/CVM to adequately staff the review teams and remain current on advances in science and technology. In addition, all post-approval requirements to account for safety throughout the lifecycle of the product remain the same. These post-approval requirements include drug experience reporting and adverse reaction evaluation.

In addition to AGDUFA, GADA supports the reauthorization of ADUFA. Many of the GADA member companies currently participate in the ADUFA 2003 user fee activities. It is estimated that our member companies paid approximately 10% of the total fees collected by FDA/CVM from ADUFA. Furthermore, GADA representatives attended the two ADUFA Public Meetings held in Rockville, MD on April 24, 2007 and March 11, 2008. GADA presented comments either at the public meeting or to the meeting docket in support of ADUFA.

We are aware that some controversy exists over the reauthorization of ADUFA, and possibly the enactment of AGDUFA. At both the 2007 and 2008 public meetings on ADUFA, a

representative of the Union of Concerned Scientists on behalf of the Keep Antibiotics Working Coalition (KAW) stated that they could not support the reauthorization of ADUFA because they believe the funding provided alters the priorities of the agency from public health to efficient approvals. Instead, KAW proposed that FDA/CVM direct resources to areas relative to antimicrobial resistance. On this issue, GADA supports the comments made to the March 11, 2008 public meeting docket by the Animal Health Institute (AHI), including their position and statements regarding antimicrobial resistance. In addition, we support the robust, science-based approval process implemented by FDA/CVM. We believe that the AGDUFA and ADUFA legislative proposals are unrelated to the issue of antimicrobial resistance. The proposed User Fees will supplement review resources – not alter the requirements necessary for approval of an animal drug or alter the post-approval surveillance requirements. Furthermore, the issue of antimicrobial resistance is outside the scope of the generic industry. The approval of a generic drug does not introduce a new drug entity to the animal population, nor does it result in increased utilization of an animal drug.

In conclusion, GADA supports the proposed legislation to authorize the Animal Generic Drug User Fee Act. We believe it is critical for the continued viability of the animal generic drug industry that the FDA/CVM review process becomes more efficient and predictable while continuing to meet the rigorous standards for drug approval. The current review process is untenable for sponsors of legal, safe and effective products and is favorable to the entities who would promote untested and illegally compounded products to fulfill unmet animal health needs.

Access to generic animal drugs that have been approved and are regulated by FDA/CVM improves the public health through improved quality of life for companion animals and increased safety of the food supply.

Sincerely,

The Generic Animal Drug Alliance

Generic Animal Drug Alliance Member Companies

Agril abs, Ltd.
AmPharmCo., American Animal Health
Bimeda Animal Health, Inc.
First Priority, Inc.
Gaddy & Associates
IVX Animal Health, Inc.
Ivy Animal Health, Inc.
Lloyd, Inc.
Med-Pharmex, Inc.
Norbrook, Inc.
PRN Pharmacal/Trophy Animal Health
Putney, Inc.
Top Choice LLC

Summary of the Generic Animal Drug Alliance's (GADA) testimony to the Subcommittee on Health of the Committee on Energy and Commerce in support of the Animal Generic Drug User Fee Act of 2008 (AGDUFA) and the Animal Drug User Fee Act Amendments of 2008 (ADUFA). June 5, 2008

The GADA is an independent professional trade organization that represents the interests of generic animal health companies before Federal regulatory agencies and Congress.

It is critical to the success of the animal health generic drug industry to have a predictable and efficient FDA/CVM review process for approval of abbreviated new animal drugs (ANADAs). The current review process is an untenable situation both for the generic drug industry and FDA/CVM. The statutory timeframe for review of an ANADA is 180 days. Currently, review cycles for ANADAs are approaching 600 days – far beyond reasonable and practical review times.

Our support for AGDUFA arises from our collective experience that ADUFA 2003 performance goals were consistently met by FDA/CVM, resulting in shortened regulatory review cycle timeframes. We were able to define the boundaries necessitated by the economics of the generic animal drug industry and still arrive at an outcome that ensures a stable, reliable revenue source to support the review process at FDA/CVM in a manner not currently met by appropriated funds.

The legislative language and associated performance goals contained within the proposal for AGDUFA are very similar to that enacted in ADUFA 2003. There are, however, several important differences between AGDUFA and ADUFA 2003: 1) AGDUFA participants will not pay an establishment fee, 2) the sponsor fee prescribed within AGDUFA is tiered to provide relief to sponsors who hold fewer ANADA approvals, 3) the performance goals for AGDUFA do not return generic application review times to statutory requirements, (180 days), rather 270 days is the highest level of performance that the generic animal drug industry can afford. While we are pleased with the overall content of the legislative proposal, additional funding requirements for FDA/CVM became apparent during our negotiations.

The purpose of AGDUFA is to supplement resources used specifically for review of applications and administration of the regulatory process - not to alter the existing stringent requirements for approval of a generic animal drug.

In addition to AGDUFA, GADA supports the reauthorization of ADUFA.

The issue of antimicrobial resistance is outside the scope of the generic industry. The approval of a generic drug does not introduce a new drug entity to the animal population, nor does it result in increased utilization of an animal drug.

GADA supports the proposed legislation to authorize the Animal Generic Drug User Fee Act. The current review process is untenable for sponsors of legal, safe and effective products and is favorable to the entities who would promote untested and illegally compounded products to fulfill unmet animal health needs. Access to generic animal drugs that have been approved and are regulated by FDA/CVM increases the public health through improved quality of life for companion animals and increased safety of the food supply.