GADA
GENERIC ANIMAL DRUG ALLIANCE

February 25, 2013

United States Senate
Committee on Health, Education, Labor, and Pensions
Washington, DC 20510-6300

Dear Honorable Members:

Thank you for the opportunity to provide testimony to the U.S. Senate Committee on Health, Education, Labor and Pensions on behalf of the Generic Animal Drug Alliance ("GADA") in support of reauthorization of the Animal Generic Drug User Fee Act of 2008 ("AGDUFA" and "AGDUFA II"). GADA is an independent professional trade organization that represents the interests of generic animal drug companies. Our members are focused on the development, FDA approval, and marketing of high quality generic drugs for livestock and pets. We seek to provide more options to ranchers, farmers, and pet owners for affordable medical care for animals.

GADA is the only trade organization that represents the interests of generic animal drug companies in the United States. We represent the majority of sponsors who hold investigational files for Abbreviated New Animal Drug Applications ("ANADAs") and ANADAs pending approval by FDA's Center for Veterinary Medicine ("CVM"). Our member companies also hold more than half of the currently approved ANADAs.

Generic Animal Drugs Are an Important Alternative to Pioneer Animal Drugs

Generic animal drugs provide significant benefits to the public by providing cost-effective alternatives to pioneer animal drugs, just like the benefits that human generic drugs provide to patients and payers. Lower cost generic options help increase access to much needed therapies for animals and contribute to the safety of the nation's food supply, the ability of pet owners to provide care to their beloved pet family members, and the treatment of diseases in animals that can be transmitted to humans.

Generic animal drugs are demonstrated safe and effective and go through a rigorous CVM approval process. They must meet the same high quality standards as pioneer animal drugs and are manufactured in FDA-inspected facilities, just like human drugs. However, generic animal drug options are not nearly as prevalent as their human generic counterparts. For example, a survey conducted by one of our member companies of Animal Drugs@FDA showed that only 7% of CVM approved drugs for dogs and cats have a CVM approved generic equivalent.

2105 Laurel Bush Road, Suite 201, Bel Air, MD 21015
Phone (443) 640-1046
Fax (443) 640-1031
Email: info@gadaonline.org
www.gadaonline.org

The potential cost savings to consumers from generic animal drugs cannot be achieved without broad availability of such drugs. Human generic drugs have demonstrated the value of generic alternatives to the public; in 2011 alone, human generic drugs saved consumers and the nation's health care system $192 billion.[1] Furthermore, greater availability of generic animal drugs means that veterinarians and consumers can make animal care decisions focused on medical reasons without having to forego treatments due to costs that are often higher than human patients pay for drug treatment. Therefore, it is crucial that we continue to explore ways to get generic animal drugs to market by providing an efficient CVM review process for approving generic animal drugs.

AGDUFA I Successfully Reduced ANADA Review Cycle Times

To encourage a robust generic animal drug industry that provides options for the health of livestock and pets, the ANADA approval process must be efficient and predictable. Prior to the implementation of AGDUFA, companies wishing to pursue generic animal drug applications had no certainty as to how long a single CVM review of their application would take, other than that it might take longer than two years. In most cases, the first review yields deficiencies and multiple review cycles are required. For each additional review the application goes to the back of the queue for another lengthy review cycle. 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 the drug and denying the public cost-effective generics to treat their livestock and pets.

An unpredictable application review timeline can prove fatal to the generic animal drug industry. Generic animal drug companies tend to be smaller and have fewer resources than their pioneer company counterparts. In the pre-AGDUFA environment, it was difficult for companies to survive and there was extreme disincentive for new companies to pursue approval of generic animal drugs.

GADA believes AGDUFA was a success in improving the efficiency and predictability of the generic review process. Since enactment of AGDUFA, CVM eliminated the review backlog and reduced the review time for a single review of an ANADA from 700 days or more to the current 270 day goal. In addition, CVM implemented multiple process enhancements and CVM-industry communications increased, including the addition of quarterly CVM-industry meetings.

[1] Generic Pharmaceutical Association Report, "Saving $1 Trillion Over 10 Years: Generic Drug Savings in the U.S. (Fourth Annual Edition, 2012)."

The establishment of review time goals created a more predictable review timeline that allows sponsors to plan for product review, approval, and launch. This helps generic animal drug options get to market more efficiently. The shorter review times also apply to post-approval manufacturing change reviews, making it easier for manufacturers to improve and modernize their manufacturing processes. Protocol reviews under investigational files also have reduced review times, which help shorten the development time prior to seeking drug approval.

While we believe AGDUFA introduced improvements to the ANADA review process, immediately after the implementation of AGDUFA the number of ANADA submissions and reactivations significantly decreased. GADA believes this apparent decrease may be because more sponsors are pursuing ANADAs through a phased approval process and those numbers are not reflected in the number of ANADAs submitted. Also, we believe the addition of user fees created a gating mechanism to ensure that sponsors only submit ANADAs if they are serious about pursuing high quality, approvable ANADAs for products that they will bring to market.

While we also saw a significant decrease in the number of generic drugs that are drug listed with FDA, we believe this is due to sponsors "cleaning up" their drug listings so as not to list products they do not market. Furthermore, we believe sponsors reduced their redundant private labels, as maintaining multiple private labels for the same product is a common practice in the animal drug industry. Thus, the reduction in the number of listed drugs does not reflect a reduction in the number of product alternatives on the market.

Since the implementation of AGDUFA, we also have seen indications that applications are on the rise and our industry is growing. During the term of AGDUFA there was an increase in the number of investigational study submissions and in the number of generic animal drug sponsors. As the only industry association for generic animal drugs, we have seen our membership increase by 53% since the passage of AGDUFA, including with some new sponsors planning to develop generic animal drugs and submit ANADAs.

During the term of AGDUFA, we have also seen new companies form to pursue generic animal drugs and already-established companies in the fields of new animal drugs and human drugs enter the generic animal drug industry. Thus, while user fees are a significant cost to a small industry, we believe the fees have not created a significant impediment to pursuing generic animal drug applications. Instead, we believe the shorter review times and predictability of the review timeline help contribute to growth of our industry and to growing employment, including in areas of the country with fewer industries to create jobs.

AGDUFA II Will Continue Shorter ANADA Review Times and Introduce More Review Process Enhancements

Entering into AGDUFA II negotiations, the generic animal drug industry had three primary goals: (1) keep user fee costs from increasing beyond the generic industry's ability to pay; (2) keep review times at least as good as in Year 5 of AGDUFA, and (3) implement more process enhancements to help reduce overall time to approval of drug applications.

The agreed upon AGDUFA II proposed legislation includes 5-year industry fees of $38,100,000 and strikes a balance between a robust revenue stream for CVM and the realities of a small but growing generics industry. The agreed upon increase in fees from AGDUFA I are to account for inflation and estimated reductions in Congressional appropriations.

GADA recognizes that user fees are intended to supplement Congressional appropriations. The generic animal drug industry is comprised of small companies and the product markets are smaller than for human drugs. Therefore, we believe it is important that the review of drug applications be primarily funded via Congressional appropriations and that appropriations continue at a level that enables FDA to meet its public health mission and the important public policy goal of providing generic drug options for farmers and pet owners.

Since the number of ANADA submissions each year is less predictable than the number of marketed products and application sponsors, under AGDUFA II the application fee will contribute a smaller percentage of total revenue than in AGDUFA I. This will provide more predictability to the amount of funding collected by CVM, which benefits both CVM and industry. This will also help keep the application fee as a gating mechanism to ensure submission of high quality applications, while helping prevent the application fee from becoming too high and serving as a significant disincentive for companies to submit applications. In exchange, the product fee and sponsor fee, which are primarily paid by established sponsors with products on the market and are therefore more predictable, will contribute an increased percentage of fees to the total user fee revenue.

GADA was not concerned predominantly with reducing the review times for single review cycles because the current 270-day review goal is a marked improvement over pre-AGDUFA timelines. While GADA would like CVM to achieve the statutory 180-day review times, the industry recognizes that the additional fees for CVM to obtain the resources needed to reach such goal are not a viable option for the generics industry. Therefore, the industry believes that

maintaining the existing timelines is an acceptable compromise while the industry grows and becomes further established.

An important industry goal for AGDUFA II was implementing substantial process enhancements that will reward high quality submissions. The enhancements will make the approval process easier to navigate for new and established sponsors, and will help reduce the overall time to approval, thus allowing more safe and effective generic products to reach the market sooner. For example, one enhancement allows for a second, shortened review cycle of 90 or 190 days, as opposed to 270 days, when deficiencies are not substantial.

Another enhancement, the two-phased Chemistry, Manufacturing, and Controls ("CMC') technical section process, enables sponsors to submit certain parts of their CMC section to an investigational file before the entire section is complete, thereby receiving earlier CVM feedback and avoiding deficiencies later in the review process that can delay approval. A third enhancement allows sponsors making significant post-approval changes to their application that receive non-substantial deficiencies to their supplement to implement their changes 30 days after submitting their deficiency responses, rather than waiting for another 270-day review cycle.

These and other improvements introduce efficiencies to the ANADA review process and help generic drug company sponsors better meet CVM's approval expectations. It is our hope that these enhancements, along with the current 270-day single cycle review timelines, will help reduce the number of review cycles and shorten the overall time to approval for ANADAs to get generic animal drug options to market sooner.

Reauthorization of AGDUFA Supports a Healthy Generics Industry to Get More Generic Animal Drugs to the Market Sooner

It is extremely important to the generic animal drug industry that AGDUFA be reauthorized. Prior to its original implementation the industry feared it would not survive, as review times dragged out and few drugs and companies made it to the end of the approval process. Furthermore, there were few incentives for new companies to pursue generic animal drugs and thus, the industry could only be sustained, and the benefits of cost saving, high quality generic drugs for livestock and pets realized, if the few existing companies remained.

AGDUFA has introduced shorter, predictable timelines for ANADA reviews, making it easier for companies to pursue generic animal drug applications. Furthermore, it has brought review process improvements and efficiencies. AGDUFA II will continue these shortened review

timelines and bring more process enhancements that will help reduce the overall time to approval. We expect that this will enable more generic products to come to market sooner and incentivize more development by generic companies, as well as more innovation by pioneer companies. Thus, reauthorization of AGDUFA is crucial to continuing to make the pursuit of generic animal drug approvals viable, to promoting a healthy generics industry, and to continuing to increase the number of generic animal drugs on the market, bringing safe and effective cost-effective drug alternatives to our nation's farmers and pet owners.

Sincerely,

The Generic Animal Drug Alliance

Generic Animal Drug Alliance Member Companies:
AgriLabs, Ltd., St. Joseph, MO
AmPharmCo, Inc., Fort Worth, TX
Aratana Therapeutics, Inc., Kansas City, MO
Argenta Limited, Metuchen, NJ
Bimeda North America, Inc., Oakbrook Terrace, IL
Ceva Animal Health, Inc., Lenexa, KS
First Priority, Inc., Elgin, IL
GDL International, St. Joseph, MO
Herschel J. Gaddy & Associates, St. Joseph, MO
Lloyd, Inc., Shenandoah, IA
Med-Pharmex, Inc., Pomona, CA
Norbrook, Inc., Lenexa, KS
Nutramax Laboratories, Inc., Edgewood, MD
Pegasus Laboratories, Inc., Pensacola, FL
Pharmgate, LLC, Ramsey, NJ
Piedmont Animal Health, Greensboro, NC
Putney, Inc., Portland, Maine
Rochem International, Inc., Ronkonkoma, NY
Sparhawk Laboratories, Inc., Lenexa, KS
Teva Animal Health, a wholly owned subsidiary of Bayer HealthCare, LLC, St. Joseph, MO
Vetoquinol USA Inc., Fort Worth, TX
VetPharm, Inc., East Rochester, NY
World Gen LLC, Paramus, NJ