



## FOR IMMEDIATE RELEASE

### **GADA Applauds the Presidential Signing of the Animal Generic Drug User Fee Act of 2008 Act will help get affordable medications to ranchers, farmers and pet owners**

Washington, DC, August 14, 2008—The Generic Animal Drug Alliance (GADA) today announced that President Bush signed into law the Animal Generic Drug User Fee Act of 2008 (Title II of H.R.6432). Under the Animal Generic Drug User Fee Act (AGDUFA), generic animal health companies for the first time will pay user fees to provide essential resources to improve generic animal drug review times—getting high quality, affordable generics to veterinarians, and animal and pet owners, faster.

Farm animals and livestock, and the majority of pets, are not covered by health insurance. Ranchers, farmers, and pet owners pay out-of-pocket for prescription medications. In contrast to human medicine where generics enter the market as soon as a drug's patents expire, few veterinary drugs have FDA approved generic versions, even years after patent expiry.

Although both new animal drugs and generic animal drugs are reviewed and approved by the Center for Veterinary Medicine (CVM), the review times for generic drug applications average more than four times as long as those for new animal drugs—preventing generic versions of medications that have long been off patent from getting to veterinarians.

“The success of AGDUFA will allow the review process for generic animal drugs to become more efficient and predictable while continuing to meet the rigorous standards for drug approval” stated Stephanie Batliner, Chair of the Generic Animal Drug Alliance and Director of Regulatory Affairs at IVX Animal Health, a GADA member company. “Generic animal drugs are essential to both pet owners and food producers to reduce costs and increase accessibility to medications.”

Jean Hoffman, CEO of Putney, a GADA member company, commented “The AGDUFA legislation marks the beginning of a new era for animal health. Much as generics have changed the face of human healthcare—making drugs more affordable for Americans—the timely availability of animal generics will help ranchers and farmers manage the cost of caring for our country's food and production animals, and allow pet owners access to lower cost medications for their companion animals who are considered members of the family.”

#### About Generic Animal Drug Alliance

The Generic Animal Drug Alliance (GADA) is an independent professional trade organization that represents the interests of generic animal health companies before Federal regulatory agencies and Congress. Member companies are focused on the development, approval and marketing of high quality generic drugs for animals and pets—making the cost of care for all animals affordable for ranchers, farmers and pet owners.

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