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January 4, 2013

Division of Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, rm. 1061  
Rockville, MD 20852

Re: Docket No. FDA-2011-N-0655-0007; Animal Generic Drug User Fee Act  
Public Meeting.

The Animal Health Institute (AHI) is the national trade association representing the manufacturers of animal health products—pharmaceuticals, vaccines, and feed additives used in modern food production and the medicines that keep pets healthy. We submit these comments to Docket No. FDA-2011-N-0655-0007, Animal Generic Drug User Fee Act Public Meeting.

AHI supports the agreement between the Generic Animal Health Alliance (GADA) and FDA as published in the Federal Register on December 5, 2012. Veterinarians and animal owners must be assured by FDA that an animal drug purported to be the same as the original product is safe and effective. AHI supports a scientifically sound generic animal drug approval process in contrast to the illegal manufacturing of new animal drugs under the guise of pharmacy compounding. Compounded products being promoted to veterinarians have not met federal standards for safety, efficacy or quality yet are being produced in large quantities and marketed in interstate commerce in clear violation of the FD&C Act.

We do take exception to a statement made by FDA in supporting the reauthorization of AGDUFA. The Federal Register announcement of the public meeting states that “...*the authorization of AGDUFA I enabled FDA's continued assurance that generic animal drug products are safe and effective, and enabled FDA's continued support for lower cost alternatives to brand name drugs for consumers.*” At the public meeting these were presented as goals of the agency. It is FDA’s legal responsibility to assure generic animal drugs have been shown to be bioequivalent, properly labeled, and manufactured to comply with appropriate quality/GMP standards. The issue of cost is a marketplace matter and not for FDA to consider in assuring generic animal drugs meet approval standards under 21 U.S.C. § 360b (b)(2). Whether or not a generic animal drug may be sold for less than a pioneer is determined by the sponsors of these products and prices will vary depending on availability and other marketing and promotional factors where they are offered for sale. Unlike human health care there are no government programs for veterinary medicine like Medicare and Medicaid where the federal government has a vested interest in the cost of prescription drugs. In the case of animal health we believe it is inappropriate for FDA to

have this as an agency goal in supporting the reauthorization of AGDUFA. It sends a message to the public that FDA believes brand name veterinary medicines are too expensive yet a large part of the cost is directly due to government regulation.

AHI supports a rigorous and scientifically based approval process for all animal drugs. However, if FDA is concerned with the cost of animal medicines the agency should strive to reduce redundant or unnecessary regulatory requirements which add to the development cost for a pioneer product and therefore affects market prices. It can currently take up to 13 years and \$100 million to achieve product approval because requirements have continued to increase with greater and more complex data being asked of sponsors to satisfy safety, efficacy, and quality standards. User fees have added to these costs. A recent Global Benchmarking Survey 2011 conducted by the International Federation for Animal Health (IFAH) indicates that development costs for a new chemical entity in the United States has increased by an average of 75% over the last 10 years. Recouping the significant R&D investment in achieving approval can take many years post approval. Current protections for animal drugs through patents and exclusivities simply are not enough in many instances to offset these investments.

AHI stands ready to engage in meaningful dialogue with the agency to explore ways to reduce regulatory costs for the approval of new products.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard A. Carnevale". The signature is written in a cursive, flowing style.

Richard A. Carnevale, VMD