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HEALTH
INSTITUTE

Representing manufacturers of animal health products

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20853

Re: Docket number 98N-0399V – Stakeholder Docket for Center for Veterinary Medicine related material – FDA Modernization Act of 1997

Comments by the Animal Health Institute:

Public Meeting on Section 406(b) of the FDA Modernization Act of 1997

AHI represents manufacturers of animal health products – the pharmaceuticals, vaccines and feed additives used in modern food production, and the medicines that keep pets healthy. As a major stakeholder in the way FDA and the Center for Veterinary Medicine carries out its responsibilities under the Federal, Food, Drug, and Cosmetic Act, we welcome the opportunity to present our views on the agency's priority setting and utilization of resources.

Let me first state that AHI greatly appreciates the close working relationship with CVM in achieving significant new legislation under the Animal Drug Availability Act, which preceded the passage of the FDA Modernization Act of 1997. The ADAA was an example of a cooperative effort between the FDA and the Coalition for Animal Health, which resulted in sweeping changes in the way animal drugs are regulated. It was only with the commitment of

the Center that the Act was able to pass the many hurdles of the legislative process. We commend Dr. Sundlof and his staff for their strong support to the process.

However, the success of that undertaking could indeed be diminished if the spirit of the legislation is lost due to a failure to carry its objectives forward. AHI and the Coalition have relayed its concerns relative to key issues such as the substitution of a multi-centered efficacy study to replace multiple investigations, a reluctance by NADE to implement pre-submission conferences, and little progress in developing workable regulatory solutions to enhance the availability of minor species/minor use products. We trust that CVM will carefully consider these concerns so that ADAA can become the success that the industry, FDA and Congress expected.

In the short time we have today to comment on the wide array of questions posed by the FDA and the Center for Veterinary Medicine, we will focus on those issues of most pressing concern to our industry. FDAMA mandated that FDA evaluate progress in addressing six objectives. We believe a key component of this evaluation is to ask what FDA can do to provide a more thorough and complete explanation of the agency's submission review process, and make explanations more available to product sponsors and other interested parties.

To this end, CVM is responsible for a drug approval process that must be science-based, predictable, and transparent. New policies are being implemented in the Center resulting in

significant new requirements, especially for antibiotics, for which the industry has not been given adequate notice and opportunity to comment upon. AHI urges the Center to address this FDA objective by following the regulations, policies and guidelines currently in place for product approval. Significant new requirements being contemplated by the Center should not be demanded of drug sponsors until the basis for such requirements has been formally communicated to the industry, been given an adequate public airing, and have been thoroughly grounded in science.

Another question raised by FDA is how to eliminate backlogs in the review process. AHI is concerned with reports from our members that suggest the approval process for new products has been experiencing problems resulting in the most significant delays in application review times in years. We support an adequate level of funding to carry out all of the Center's public health responsibilities. However, it is necessary to prioritize those functions of most importance to the Center's mission and those of less importance where resources can be reduced.

The FDA Center for Veterinary Medicine's mission statement as presented to stakeholders is to be a consumer protection organization fostering "public and animal health by approving safe and effective products for animals..." We emphasize that this mission should be the guiding principle in allocating resources and priorities to the Center activities.

It is our view that the best way to protect the public health is to ensure the availability of safe and effective animal drugs and feed additives.

We are concerned with the apparent re-direction of priorities from product application review to other activities. We understand that the Center has received both additional funding, and additional responsibilities, under the President's Food Safety Initiative. While this is an important program, we fear that an increased emphasis in the Center on its potential role in microbial food-borne illness may interfere with its prime directive to evaluate the safety and efficacy of animal drugs and feed additives.

We urge CVM to direct the necessary resources to the drug approval process to maintain a system, which is responsive and efficient in meeting statutory deadlines. We are encouraged by the Center's willingness to implement a phased review system for new animal drugs. Phasing of the review process is important to both the agency and the industry by permitting a more logical step by step process for drug development and application review. The industry strongly supports further efforts by CVM to incorporate phased application review as a routine procedure for NADA's.

Question have also been posed as to what functions the Center can "contract out," and whether it should impose "user fees." Regarding the issue of user fees, AHI has steadfastly opposed user fees for NADA review. User fees or other forms of non-federal funding are not

appropriate for those functions that are the responsibility of government in ensuring the safety of the food supply from food-borne hazards.

The industry is not opposed to the Center finding ways to improve or fill human resource gaps in its application review process by seeking expert outside review of certain sections of the application, as long as the quality of the review is maintained and review times are maintained. For example, we could support the outside review of laboratory animal toxicology and pathology studies. Such studies are usually conducted under accepted protocols and outside scientific expertise is readily available. Another potential area for consideration of outside expertise is with the statistical evaluation of efficacy studies, which is critical to drawing conclusions from well-controlled studies.

Let me comment on enforcement of violations of the Food, Drug, and Cosmetic Act. AHI views this function as critical in protecting the integrity of the drug approval process and those pharmaceutical companies legally marketing products meeting the requirements of the Act. We are concerned that the majority of effort and resources being expended by the Center on surveillance and compliance functions appears to be directed at these companies marketing approved drug products. More effort needs to go into preventing the distribution of illegally marketed or compounded products and those practices which are clearly outside of the provisions of the recently published AMDUCA regulations, which restrict the extra-label use of human

drugs in lieu of approved food animal drugs for which there is established safety and efficacy data.

I would like to comment briefly on a question posed by CVM regarding the mix of activities being under taken in the Center toward international harmonization. While the international efforts listed in the question are important, AHI supports a strong focus on Codex Alimentarius and the Veterinary International Cooperation on Harmonization (VICH) activities as having the most importance to harmonization. AHI and CVM have partnered closely in both the Codex Committee on Residues of Veterinary Drugs in Foods and the VICH. These programs stand to be the most productive, in our view, in bringing science-based harmonization to the evaluation of new animal drugs because they are formal cooperative programs between the regulated industry and government agencies in various parts of the world.

We thank you for your time today to provide some of our views. We reserve our right to submit written comments to the docket by the September 11th deadline. We look forward to addressing these issues and challenges in setting priorities for the CVM. We share Dr. Sundlof's goal of achieving higher levels of regulatory certainty and efficiency. All members of CVM have AHI's commitment to be a creative, positive force in developing solutions to the issues we face today and in the future.