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Manager, Regulatory Affairs

April 30, 2007

Division of Dockets Management (HFA-305)  
Food and Drug Administration, HHS  
5630 Fishers Lane, Room 1061  
Rockville, MD 20857

**Re: Docket No. 2007D-0021; Draft Guidance for Industry on Advisory Committee Meetings: Preparation and Public Availability of Information Given to Advisory Committee Members; Availability**

The ANIMAL HEALTH INSTITUTE (“AHI”) submits these comments to Docket No. 2007D-0021; Draft Guidance for Industry on Advisory Committee Meetings: Preparation and Public Availability of Information Given to Advisory Committee Members; Availability. AHI is the national trade association representing manufacturers of animal health products – the pharmaceuticals, biological products and feed additives used in modern food production, and the medicines that keep livestock and pets healthy. AHI member companies represent the majority of animal pharmaceuticals and animal insecticides, as well as serving a significant segment of the world market. As such we have a tremendous interest in the timing and content of information available to Veterinary Medical Advisory Committee (VMAC) members and the public.

The function of VMAC according to the VMAC Charter states, “The Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational new animal drugs, feeds, and devices for use in the treatment and prevention of animal diseases and increased animal production, and makes appropriate recommendations to the Commissioner of Food and Drugs regarding scientific issues and regulatory policies.” The guidance document adequately describes the content sponsors may submit to the advisory committee and how it should be labeled in an effort to prevent public availability of materials that contain information claimed to be exempt from disclosure. Additionally, AHI believes that providing the committee members with the briefing materials two-three weeks in advance of the meeting (as stated in the guidance) is sufficient time to review the information. It is not possible, however, to guarantee the advisory committees will indeed review the materials prior to the meeting regardless of the amount of time allotted to do so. AHI would like to suggest one minor change to the guidance document relative the timeline appendices. In an effort to remain consistent, the first FDA Action listed in Appendix B, “We intend to notify the sponsor that we are taking an issue directly relevant to the sponsor to an advisory committee” (fifty-five business days before the meeting) should be added to Appendix A.

AHI does not recommend additional changes to the guidance at this time, but would like FDA to clarify some issues regarding comments/presentations by interested persons other than the sponsor. Because VMAC meetings are open to the public except as may be determined otherwise by the Commissioner, presentations by outside parties do impact the outcome of VMAC deliberations. Any submissions by those parties should have to follow the same guidelines as those set forth for the sponsor. The information submitted by interested persons is not made publicly available prior to the advisory committee meetings and has not been reviewed for scientific accuracy. The information is made publicly available only through the VMAC transcript or posting of public comments to the Docket when the party is not physically present at the meeting. Are such comments made available to committee members under a different timeline than the public availability which varies for each Docket? It is concerning that an advisory committee decision may be persuaded by interested parties' comments that have not been thoroughly checked for accuracy or because members of the committee have not thoroughly reviewed the briefing materials provided by the sponsor or Center.

AHI appreciates the opportunity to comment on this guidance document and sincerely hopes that the information provided will be considered and incorporated in the finalization of this document. Should you have any questions, please contact AHI at (202) 637-2440.

Sincerely,

A handwritten signature in cursive script that reads "Madeline Palla".

Madeline Palla

Manager, Regulatory Affairs