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

Re: Docket No. FDA-2011-D-0784; Draft Guidance for Industry on Evaluating the Effectiveness of Anticoccidial Drugs in Food-Producing Animals; Availability

The ANIMAL HEALTH INSTITUTE (“AHI”) submits these comments to Docket No. FDA-2011-D-0784; Draft Guidance for Industry on Evaluating the Effectiveness of Anticoccidial Drugs in Food-Producing Animals (GFI #217). 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.

AHI would like to offer the following comments on Draft Guidance for Industry #217:

The changes made in Guideline #217 are an improvement to Guideline #40 “Draft Guideline for the Evaluation of The Efficacy of Anticoccidial Drugs and Anticoccidial Drug Combinations in Poultry,” dated April 1992. GFI #217 is much more detailed in some areas than #40, and overall the changes are positive in that they remove some questions or problems that may have arisen due to interpretation in the past. However, these changes add numerous details that may make protocol development more challenging and time consuming. AHI acknowledges that once the protocol is developed and concurred upon by CVM, the study will provide more robust data, and a stronger protocol may help eliminate problems during review by CVM.

We note that there is more emphasis on feed mixing, sampling and nutrient content determination within specific criteria. Getting the feed correct from a drug inclusion and nutrient level aspect will be very important and potentially more difficult than in the past. The decision tree added in Appendix 2 is also of note and points out the importance of determining CVM and sponsor pre-approved or agreed upon success criteria prior to launching any pivotal trials.

Thank you in advance for your consideration of these comments. Should you have any questions, please do not hesitate to contact AHI at (202) 637-2440.

Sincerely,



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