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

Re: Docket No. FDA–2010–N–0307; Agency Information Collection Activities; Proposed Collection; Comment Request; “Antiparasitic Drug Survey”

The ANIMAL HEALTH INSTITUTE (“AHI”) submits these comments to Docket No. FDA–2010–N–0307; Agency Information Collection Activities; Proposed Collection; Comment Request; “Antiparasitic Drug Survey”. 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 collection of information that could affect the regulation of antiparasitic drugs.

The results obtained from the proposed survey would likely include a diversity of opinion and conjecture on antiparasitic drug resistance based on inconclusive scientific data and/or anecdotal information. Any conclusion(s) drawn from the results of such a survey would be neither appropriate nor adequate to develop the agency’s position with respect to the regulation of antiparasitic drugs. If the agency wishes to obtain credible information on this topic, then we recommend that FDA initiate consultation with appropriate experts in the field and develop an appropriate science-based strategy to elucidate the true impact of various husbandry methods and antiparasitic regimes on resistance. We believe this approach will be a benefit to all concerned entities, including the general public.

If FDA intends to move forward with the proposed survey, we offer the following comments and questions for consideration:

- FDA should publish the survey questions in the Federal Register for comment prior to finalizing them for the pre-test and actual survey.
- The Federal Register states FDA will use a web-based tool for the survey. How will FDA decide who to survey (i.e. will FDA solicit volunteers from a specific association such as AAVPT, or will a survey request be posted somewhere on the web)?
- Who will review and compile the survey results?
- How does FDA plan to publish the results? Will the results be made public? Industry would like to see the results of the survey prior to sharing, or at the same time as they are shared, with the veterinary parasitology community or public.

We would also like to point out a typo in Table 1. – Estimated Annual Reporting Burden on Page 39948 of the Federal Register. The Total Hours for the Survey should list 33.0, not .33.

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,

Samata Veluvolu
Manager, Regulatory Affairs