

Samata Veluvolu
Manager, Regulatory Affairs

August 20, 2012

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

Re: Docket No. FDA-2012-D-0419; Draft Guidance for Industry on Active Controls in Studies To Demonstrate Effectiveness of a New Animal Drug for Use in Companion Animals; Availability

The ANIMAL HEALTH INSTITUTE (“AHI”) submits these comments to Docket No. FDA-2012-D-0419; Draft Guidance for Industry #204 “Active Controls in Studies To Demonstrate Effectiveness of a New Animal Drug for Use in Companion Animals”. 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.

After reviewing the draft guidance, AHI does not believe non-inferiority studies are made any more feasible for the animal health industry to design and perform. On page 6, sections II.I. and II.J., we are concerned about using two-sided confidence intervals when the test is clearly one-sided -- that is why it is called a non-inferiority test, and not a “different by a specified amount” test. To then follow this by selecting only one end of the two-sided interval is essentially changing the significance level from 95% to 97.5%, with the concomitant increase in sample size. Since this is for a binomial response, this could mean increasing sample size substantially. The end result is that these studies are only of interest in the few cases where negative-controlled studies pose serious concerns for the welfare of the study animals.

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