

Madeline K. Palla
Manager, Regulatory Affairs

July 18, 2008

Division of Dockets Management
U.S. Food and Drug Administration
HFA-305
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 2008N-0326: New Animal Drugs; Cephalosporin Drugs; Extralabel Animal Drug Use; Order of Prohibition

The ANIMAL HEALTH INSTITUTE (“AHI”) requests a 60-day extension of the comment period and effective date for Docket No. 2008N-0326: New Animal Drugs; Cephalosporin Drugs; Extralabel Animal Drug Use; Order of Prohibition published by FDA in the *Federal Register* on July 3, 2008.

AHI is the national trade association representing manufacturers of animal health products – the pharmaceuticals, vaccines and feed additives used in modern food production, and the medicines that keep livestock and pets healthy.

Due to significant concerns with respect to the intended scope of this prohibition being raised in the veterinary community and the potential effect on animal health, we request additional time to thoroughly review the rule and the Agency’s justification for prohibiting extralabel uses in all food animal species. Additionally, AHI will need time to analyze and comment on the impact to our members’ customer base and the risk posed to the treatment and control of animal diseases.

We appreciate your consideration of our request and look forward to hearing from you.

Sincerely,



Madeline Palla
Manager, Regulatory Affairs