

Madeline K. Palla
Manager, Regulatory Affairs

September 26, 2006

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

Re: Docket No. 2005N-0403, OC 1994634. Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs that are Regulated Under a Biologics License Application, and Animal Drugs: Pages 51276-51357 [FR Doc. 06-7172]

The ANIMAL HEALTH INSTITUTE (“AHI”) requests a 60-day extension of the comment period for Docket No. 2005N-0403, OC 1994634. Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs that are Regulated Under a Biologics License Application, and Animal Drugs: Pages 51276-51357 [FR Doc. 06-7172] published by FDA in the *Federal Register* on August 29, 2006.

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 the potential impact on our industry of this proposed rule, we request additional time to thoroughly review the document, analyze the impact on our industry and provide comments to the Docket. We appreciate your consideration of our request and look forward to hearing from you.

Sincerely,



Madeline Palla
Manager, Regulatory Affairs