

Samata Veluvolu  
Manager, Regulatory Affairs

April 23, 2014

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

**Re: Docket No. FDA-2013-D-1675; Draft Guidance for Industry on New Chemical Entity Exclusivity Determinations for Certain Fixed-Combination Drug Products; Availability**

The ANIMAL HEALTH INSTITUTE (“AHI”) submits these comments to Docket No. FDA-2013-D-1675; Draft Guidance for Industry on New Chemical Entity Exclusivity Determinations for Certain Fixed-Combination Drug Products. 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.

We appreciate the rationale that the agency is using to facilitate the development of important new fixed combinations for human use. New animal drug applications approved under section 512(b)(1) of the Act [21 USC § 360b(b)(1)] are governed by the identical exclusivity provisions afforded new human drugs. The animal health community could also benefit from this new interpretation of a drug in the context of exclusivity protections. Animal patients provide challenges to proper medication. Certain fixed combinations are invaluable to the effective treatment of serious conditions.

Since a drug under the Act applies to articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, we respectfully request the agency consider extending the new interpretation of a “drug” as a “drug substance” for purposes of exclusivity provisions, to new fixed animal drug combinations as well.

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