

Samata Veluvolu
Manager, Regulatory Affairs

November 1, 2011

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

Re: Docket No. FDA-2011-D-0588; International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Draft Guidance for Industry on Pharmacovigilance of Veterinary Medicinal Products: Electronic Standards for Transfer of Data; Availability

The ANIMAL HEALTH INSTITUTE (“AHI”) submits these comments to Docket No. FDA-2011-D-0588; International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Draft Guidance for Industry on Pharmacovigilance of Veterinary Medicinal Products: Electronic Standards for Transfer of Data. 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 initiatives that promote the international harmonization of regulatory requirements.

AHI would like to offer the following comment on Draft Guidance for Industry #214/VICH GL35:

- On Page 11 of 16, B4 “Dechallenge-Rechallenge Information” and B5 “Assessment of AE” should be product specific.

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,



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Manager, Regulatory Affairs