ANIMAL HEALTH INSTITUTE

Representing manufacturers of animal health products

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President & CEO

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

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Re: Docket No. OOD- 1632 International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Draft Guidance on "Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports (AER's)" (VICH GL24)

The ANIMAL HEALTH INSTITUTE ("AHI") submits these comments to the Draft Guidance on Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event,, Reports, VICH GL24 published by the Food and Drug Administration in the *Federal Register* on Monday, December 18, 2000.

AH1 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, AH1 has been actively involved in the VICH process, and has already had significant input into the VICH GL24 Pharmacovigilance document. As a whole, AHI is very pleased with the draft document and believes, with minor comment, that the document is sound and should be adopted by FDA.

We understand the challenge facing the VICH pharmacovigilance working group, and we understand the intended scope of this initial document. To be fair, we should point out that the group's counterpart within ICH has worked over several years and generated many guidelines. However, there are several issues that the content of the guideline raises, some of which should be addressed in this document and some that are for additional guidelines.

## Uniform Grouping of Animals

Pharmacovigilance, particularly the analysis of spontaneous reports of adverse experiences, can be a valuable tool in evaluating and comparing trends that reflect a product's performance in the field. However, either within a company or regulatory body, such analysis of adverse experience reports can only have relevance if there is a uniform approach to the grouping of the animal(s) identified within a report. This should be of the utmost importance to regulatory agencies because they may receive a number of reports on the same biologic, drug or class of product. If the method of identifying or grouping animals for reporting varies from company to company, then there is little value to the regulatory agency in evaluating trends across classes. Therefore, we believe the VICH working group should address the appropriate grouping for reporting purposes. We believe that only one animal or a medically appropriate

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grouping of animals, which exhibit similar clinical signs and were treated with one or more common product, should be included in a single report.

**Dictionary**

Use of a common dictionary of "adverse event" terms is also important in order to assure that terms are used consistently, as well as to allow comparison between products and across product classes. The dictionary must have standardized groupings of terms, and the size of the dictionary must be limited to a manageable size, taking into account the practical realities of the animal health industry. Moreover, industry and government should partner together in the development, implementation, and ongoing maintenance necessary to keep an "adverse event" dictionary up to date and useful. Some type of joint industry and government oversight board could best meet these needs. We believe the VICH working group should address the selection and use of such a dictionary.

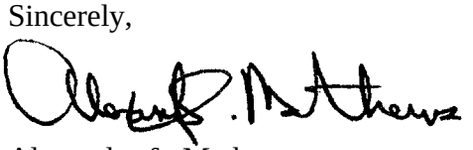
**Serious Adverse Events**

It is important to effect harmonization on the reporting requirements for "Serious Adverse Events." Currently, the three regions all differ in the timeframes required for reporting serious adverse events. The requirements should be harmonized among the regions in a manner that allows appropriate and thorough investigation of suspected events by the company prior to reporting to the regulatory authority. Only in this manner will regulatory authorities receive sufficient useful information for evaluation and decision making. We believe that the regions should not require reporting of a serious adverse event as defined in the guideline any sooner than 15 business days from the date of submission to the company. This would provide for the prompt reporting of suspected serious adverse events, while allowing adequate time for investigation, and harmonize reporting among the regions through a compromise among the participants.

**Periodic Summary Update**

The document addresses the periodic summary update (PSU). However, it is unclear whether this document intends for PSUs to be utilized on a global or regional basis. The most efficient use of the PSU would utilize a single PSU report that could be submitted to the requesting authority. In order to generate such a report, the VICH working group should address defining a universal product "birtbdate," a single format for a PSU report, and development of consistent definitions of what is considered an "unexpected" adverse event, as well as developing consistent definitions of product groupings.

Sincerely,



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