

Alexander S. Mathews
President and CEO

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July 18, 2003

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

Re: Docket No. 03D-0051

The ANIMAL HEALTH INSTITUTE ("AHI") submits these comments to the Draft Guidance for Industry on "Pre-Approval Information for Registration of New Veterinary Medicinal Products for Food-Producing Animals with Respect to Antimicrobial Resistance," VICH Topic GL27 published by FDA in the *Federal Register* on Thursday, June 12, 2003.

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. AHI has been actively involved in the VICH process, and has already had significant input into the VICH GL27 document.

The VICH process is a valued means to harmonize drug approval requirements among the U.S., E.U. and Japan. In order to accomplish this goal, a stepwise approval process has been agreed and successfully followed. With respect to GL27, authorized by all the appropriate industry and regulatory representatives of the U.S., E.U., and Japan to advance the document to Step 4. The current document that has been posted for comments is not the document that was agreed to at Step 4, but rather a version that has been edited by the FDA CVM. The AHI has used a "red line" version of the CVM version to make specific comments to the document. The majority of the text changes have been made as editorial in nature to strive for consistency in the wording of the Objective of the document, the Introduction's statement of purpose, and Section 3. The objective of the document is to establish harmonized technical guidance for registration of therapeutic antimicrobial veterinary medicinal products intended for use in food-producing animals with regard to characterization of the potential for a given antimicrobial agent to select for resistant bacteria of human health concern.

With respect to the current CVM version of the Step 4 document, one of the most obvious changes is the deletion of much of the Introduction. It is the AHI position that the Introduction represents a balanced scientific representation of the complex situation as to the

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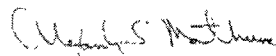
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origin and transfer of antibiotic resistant bacteria between humans and food animals. It is not clear as to the why the CVM supported the scientific assessment of the antibiotic resistance within the Introduction, but has opted to delete it at this point. It would be helpful to the VICH working group for the CVM to provide scientific data to justify the reversal of its acceptance of the original introduction. The inclusion of the Introduction is important to the document as it provides an appropriate context within which the specific pre-approval information is useful. At the present time, AHI sees no valid scientific reason for the deletion of the Introduction and supports the wording of the original Step 4 version.

For ease of review we have attached a grid containing our recommended changes and rationale for the changes. Additionally, we have provided a redline version of the guidance document highlighting our recommended changes. We appreciate the opportunity to comment on this draft document. If you have questions or need additional information, please do not hesitate to contact us.

Sincerely,



Alexander S. Mathews

Attachments