

February 18, 2005

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

**Attn: Docket No. 2004N-0479; Draft Risk Assessment of Streptogramin Resistance in Enterococcus faecium Attributable to the Use of Streptogramins in Animals; Availability—Comments**

Dear Sirs,

Phibro Animal Health (PAH) is the world's only producer of virginiamycin, and holds the NADAs for its approval in the US. Accordingly, we have a great interest in the Draft Risk Assessment of Streptogramin Resistance in Enterococcus faecium Attributable to the Use of Streptogramins in Animals (Docket No. 2004N-0479). As such, we submit the following comments on the draft document.

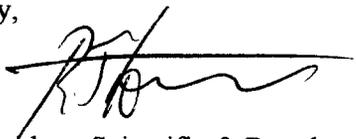
First, we congratulate the authors for producing a comprehensive risk assessment of high quality that deals with a very complicated and controversial subject. Although we have made many comments and suggestions that we feel would improve the final version of this risk assessment, we believe that, as written, this assessment is superior to any qualitative risk assessments that have been proposed.

Our detailed comments follow in an attachment to this letter. We would like to highlight a few key points:

- Although the authors state that the risk assessment makes no "firm conclusions as to whether, and, if so, how much, the use of streptogramins in food animals contributes to the occurrence of streptogramin-resistant *E. faecium* infections in humans", we feel that this extensive review of all available data, after 30+ years of virginiamycin use in animals, demonstrates that no hazard exists.
- The authors have provided extensive data that food attribution cannot possibly be the cause of 100% of SREf in humans (and in fact, the data seem to indicate that 0% or near-0% is most likely); therefore PAH believes that use of "a second scenario that assumes a food pathway attribution factor of 100%" is misleading and should be removed from the report.
- The authors failed to recognize that linelozid is now the first line of defense against VREf; PAH feels that all model calculations should be adjusted to reflect this.
- The authors have not included the most recent data on Synercid<sup>®</sup> sales/use; PAH notes that Synercid<sup>®</sup> sales have declined by 40% since the report was written and that these data should be reflected in the final report.

We remain available to further discuss our comments and look forward to publication of the final version of the risk assessment.

Sincerely,



Vice President, Scientific & Regulatory Affairs

Attachment

**2004N-0479**

**CS**