

12/17/04 09:17:11 AM

December 16, 2004

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

**Subject: Docket No. 2004N-0479; Request for comment deadline extension**

Dear Docket Manager,

Phibro Animal Health hereby requests a 60-day extension (from the original date of January 24, 2005) on the comment period for Docket No. 2004N-0479, Draft Risk Assessment of Streptogramin Resistance in *Enterococcus faecium* Attributable to the Use of Streptogramins in Animals; Availability.

Phibro Animal Health is the only company marketing virginiamycin, the streptogramin that is the subject of the draft risk assessment, in the US. This product, known as Stafac, is Phibro Animal Health's most economically important product, and thus anything that may have a regulatory impact on it is of extreme importance to us.

Phibro Animal Health is currently in the process of moving our office. Between the office move and the holidays (the Federal Register announcement was made the day before thanksgiving; the 60 day comment period also includes Christmas and New Years), we feel we do not have adequate time to comment to the docket given the current deadline. We feel that, given the importance of this docket to our business, a 60-day extension is warranted.

Sincerely,



Paul F. Duquette  
Director, Global Regulatory Affairs  
Phibro Animal Health  
65 Challenger Road, 3<sup>rd</sup> floor  
Ridgefield Park, NJ 07660

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