

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0479]

DMP
Reply Date 1-4-05
Expiration Date 1-5-05
Officer [Signature]

Draft Risk Assessment of Streptogramin Resistance in Enterococcus faecium Attributable to the Use of Streptogramins in Animals; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to February 23, 2005, the comment period for the notice that appeared in the **Federal Register** of November 24, 2004 (69 FR 68384). In the notice, FDA requested comments on a draft risk assessment of the potential impact that food-animal use of streptogramin antimicrobials has on the resistance to chemically similar streptogramins used to treat human enterococcal infections. The agency is taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: Submit written and electronic comments by February 23, 2005.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Barry Hooberman, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-8557, e-mail: bhooberm@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:**I. Background**

In the **Federal Register** of November 24, 2004 (69 FR 68384), FDA published a notice with a 60-day comment period to request comments on a draft risk assessment of the potential impact that food-animal use of streptogramin antimicrobials has on the resistance to chemically similar streptogramins used to treat human enterococcal infections. The veterinary drug of interest in this risk assessment is the streptogramin, virginiamycin, a drug approved for use in chicken, turkey, swine, and cattle feed. FDA will consider information received during the comment period in its preparation of a final risk assessment.

The agency has received a request for a 60-day extension of the comment period for the notice. This request conveyed concern that the current 60-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the notice.

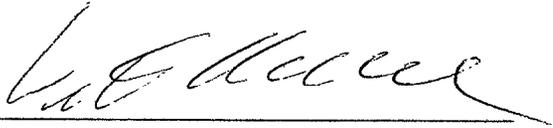
FDA has considered the request and is extending the comment period for the notice for an additional 30 days, until February 23, 2005. The agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying the preparation of the final risk assessment.

II. Request for Comments

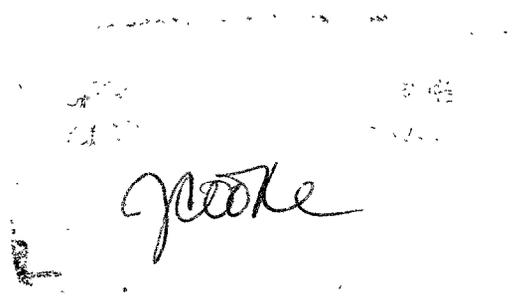
Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this

document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 28, 2004
December 28, 2004.



William K. Hubbard,
Associate Commissioner for Policy and Planning.



> [FR Doc. 04-⁵????? Filed ??-??-04⁵; 8:45 am]

BILLING CODE 4160-01-S