

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0479]

Draft Risk Assessment of Streptogramin Resistance in *Enterococcus faecium* Attributable to the Use of Streptogramins in Animals; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of, and is requesting comment 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.

DATES: Submit written or electronic comments on the draft risk assessment document by [*insert date 60 days after date of publication in the **Federal Register***]. FDA will accept comments, data, and information after the deadline, but to assure consideration by the agency, we must receive comments by this date.

ADDRESSES: Single copies of this draft risk assessment are available from the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Please enclose a self-addressed, adhesive label to assist that office in processing your request.

This draft risk assessment is also available on the Internet at: <http://www.fda.gov/cvm/antimicrobial/antimicrobial.htm>.

Send written comments on this draft risk assessment 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.accessdata.fda.gov/scripts/oc/dockets/commentdocket.cfm>.

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 April 19, 2000 (65 FR 20992), FDA's Center for Veterinary Medicine (CVM) announced plans to develop a prototypic risk assessment (RA) model that accounts for the transfer of resistance determinants from bacteria in food-producing animals to bacteria in humans. CVM also requested comments on their approach to the RA model, requested that scientific data and information relevant to the conduct of the RA be submitted, and indicated its intention to work with stakeholders to assess potential risks.

The outcome of our work is a document entitled "Draft Risk Assessment of Streptogramin Resistance in *Enterococcus faecium* Attributable to the Use of Streptogramins in Animals." This draft risk assessment specifically addresses the link between the use of the streptogramin antimicrobial, virginiamycin, in food-producing animals and the development of resistance to the related streptogramins, quinupristin-dalfopristin, used to treat human enterococcal infections. *Enterococcus* bacteria include commensal strains

normally present in the intestines of animals and man. This risk assessment focuses on the opportunistic pathogen *Enterococcus faecium*.

In an effort to better ensure broad awareness of this **Federal Register** notice, FDA will make copies available through the FDA Dockets Listserv (<http://www.fda.gov/ohrms/dockets/FDAMAIL/DMBemaillist.htm>). To be added to any of FDA's free e-mail subscription services go to: <http://www.fda.gov>. Click on "Subscribe to FDA's E-mail Lists", then follow the instructions provided.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 13, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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