DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

VMF 3577 C-0019, C-0020 & C-0021

JUN 13 1996

CONFIDENTIAL

Donald A. Gable, D.V.M.
Director, Special Projects
Regulatory Affairs
Fermenta Animal Health Company
P.O. Box 338, 15th & Oak
Elwood, KS 66024

Dear Dr. Gable:

This is in response to your letters dated June 22, 1995, March 22 and April 9, 1996, pertaining to Veterinary Master File 3577 for NOPTRACIN MD 50, Bacitracin Methylene Disalicylate Type A Medicated Article. The April 9 letter contained the agenda for the meeting held with you on May 31, 1996, at the Center for Veterinary Medicine.

We have reviewed your submissions and we have the following comments which were also discussed at the May 31 meeting:

1. Your BMD Type A medicated article is listed under 558.15 and is, therefore, eligible for the interim privileges provided by the regulation. Based on a review of available files, we were not able to establish that your product has ever been approved either by a form 6 or otherwise. However, as previously noted, this does not prevent you from marketing your product at this time under the provisions of 588.15.

2. You do not need a review or approval from CVM for the alternate manufacturing site for bacitracin methylene disalicylate raw material or feed grade to support marketing. Your product is unapproved and 558.15 does not require approval of manufacturing sites as a condition of interim marketing of unapproved products. You will, of course, be subject to inspection for compliance with GMPs.

3. However, in anticipation of attaining approval of your product you may want to establish an INAD, submit manufacturing information to your Master File and request a phased review of the information.

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In closing, we also note, as discussed at the meeting, that the Center does not plan to begin the process of revoking 558.15 interim marketing privileges in the immediate future. Moreover, since the process involves notice-and-comment rulemaking, it will take a considerable period of time to conclude such an action once it is initiated. You should contact the Division of Therapeutic Drugs for Food Animals to discuss specific requirements for approval of your product.

Sincerely yours,

Andrew J. Beaulieu, D.V.M
Deputy Director, Therapeutic
& Production Drug Review
Office of New Animal
Drug Evaluation