DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

SP 03P-0108/CP1

JUN 4 2003

Linda M. Duple
Regulatory Affairs Coordinator
Bimeda, Inc.
2836 Dolliver Park Avenue
Lehigh, IA 50557

Dear Ms. Duple:

We refer to your Suitability Petition filed March 20, 2003, on behalf of Cross Vetpharm Group, Ltd., in which you requested permission to submit an abbreviated new animal drug application (ANADA) for a generic product with a change of strength that differs from that of an approved new animal drug. The proposed pioneer product is Elanco Animal Health's Apralan (apramycin sulfate) which is intended for use in pigs (NADA 106-964).

Your proposed product differs from the pioneer product in strength. The proposed generic product is intended to deliver the same amount of active ingredient per pound of body weight.

Change in strength is one of the five variances in the pioneer product which can be considered through a Suitability Petition under section 512(n)(3) of the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended. We are required to approve the petition unless we determine that investigations must be conducted to establish the safety and effectiveness of the proposed generic product.

Your Suitability Petition is approved. Approval of the Suitability Petition does not alter the requirements for approval of the ANADA, nor assure approval of the ANADA. Please include a copy of this letter in your generic application.

An *in vivo* bioequivalence study to demonstrate bioequivalence between the pioneer and the generic products will be required. We recommend that you submit protocols for our evaluation before initiating any studies.

We will conduct a definitive labeling review when the ANADA for the proposed generic product is submitted to the Center. The generic labeling should be a verbatim copy of the approved labeling for the pioneer, with certain allowable differences, such as manufacturer's tradename and the changes approved in this petition.

03P-0108

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You may contact Dr. Lonnie W. Luther, Generic Animal Drug Team, telephone 301-827-8549, for any questions on the specific requirements for the ANADA submission.

Sincerely yours,

Steven D. Vaughn DVM

Steven D. Vaughn, DVM
Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine