



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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SP 03P-0523/CP1

DEC 4 2003

Karen A. Sisson
4776 E. Horse Mesa Trail
Queen Creek, AZ 85242

Dear Ms. Sisson:

We refer to your Suitability Petition filed November 12, 2003, in which you requested permission to submit an abbreviated new animal drug application (ANADA) for a generic product with a dosage form that differs from that of an approved new animal drug. The proposed pioneer product is Merial's Zimecterin[®] Gold Paste (ivermectin/praziquantel) which is intended for use in horses (NADA 141-214).

Your proposed product differs from the pioneer product in dosage form. The proposed generic product is a granule/crumble, which can be administered orally either alone, as a top dress, or in a small amount of feed, whereas the pioneer is a paste. The proposed generic product is intended to deliver the same amount of active ingredient per pound of body weight, and is intended for individual animal treatment, as is the pioneer paste.

Change in dosage form 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.

In addition to an *in vivo* bioequivalence study to demonstrate bioequivalence between the pioneer and the generic products, we will require you to conduct a palatability study with the generic product. Palatability is not directly related to effectiveness. A palatability study may be conducted to demonstrate whether horses, particularly foals 6-8 weeks of age, can and will consume an adequate amount of the proposed drug product when administered by feeding alone, as a top dress, or in a small amount of feed, and more than one palatability study may be necessary for these methods of oral administration. Palatability studies may be required in an ANADA with regard to the change in dosage

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form under section 512(n)(1)(D) of the FFDCa. 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.

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,

Bernadette J. Junkan, DVM, Ph.D.
Deputy Director
for Steven D. Vaughn, DVM
Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine