

Food and Drug Administration
Rockville MD 20857

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SP 04P-0551/CP1

JAN 28 2005

Intervet, Inc.
Attention: Mary K. Hagler, MS
Senior Regulatory Affairs Specialist – Pharmaceuticals
29160 Intervet Lane
P.O. Box 318
Millsboro, DE 19966-0318

Dear Ms. Hagler:

We refer to your Suitability Petition filed December 21, 2004, in which you requested permission to submit an abbreviated new animal drug application (ANADA) for a generic product with a change in strength and change in dosage form that differ from that of an approved new animal drug. The proposed pioneer product is Merial Ltd.'s UlcerGard™ (omeprazole) which is intended for use in horses, NADA 141-227.

Your proposed product differs from the pioneer product in strength and dosage form. The proposed generic product is a tablet, which can be administered orally 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 strength and change in dosage form are two 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, which you have acknowledged. 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

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proposed generic drug product when administered. More than one palatability study may be necessary, depending on the method(s) of oral administration. Palatability studies may be required in an ANADA with regard to the change in dosage form under section 512(n)(1)(D) of the FDCA. We recommend that you submit protocols for our evaluation before initiating any studies.

The pioneer product is protected by an exclusivity that expires on February 18, 2007, granted for the effectiveness at 1 milligram per kilogram per day for the prevention of gastric ulcers in horses. Furthermore, the pioneer product is protected by a patent which does not expire until April 4, 2015.

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. Daniel A. Benz, Generic Animal Drug Team, telephone 301-827-0223, for any questions on the specific requirements for the ANADA submission.

Sincerely yours,



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