



OCT 8 2004

SP 04P-0372/CP1

Intervet Inc.
Attention: Ruth LaCrosse-Vernimb
Manager, Regulatory Compliance and Quality Assurance - Pharmaceuticals
405 State Street
P.O. Box 318
Millsboro, DE 19966-9906

Dear Ms. La-Crosse-Vernimb:

In your Suitability Petition filed August 20, 2004, you requested permission to submit an abbreviated new animal drug application (ANADA) for a generic product with a change in dosage form that differs from that of an approved new animal drug. The proposed pioneer product is Pfizer's Rimadyl[®] (carprofen) Caplets which is intended for use in dogs (NADA 141-053).

Your proposed product differs from the pioneer product in dosage form. The proposed generic product is a scored chewable tablet, which can be administered orally whereas the pioneer is a caplet. 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 caplet.

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.

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.

2004P-0372

PAV-1

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. Palatability studies may be required in an ANADA with regard to the change in dosage form under section 512(n)(1)(D) of the FFDCA. We recommend that you submit protocols for our evaluation before initiating any studies.

The pioneer product is protected by an exclusivity that expires September 21, 2004 for the once a day use for relief of pain associated with osteoarthritis in dogs. There is another exclusivity that expires on July 8, 2005, for control of postoperative pain associated with soft tissue and with orthopedic surgery in dogs.

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 other appropriate changes.

You may contact Dr. Lonnie W. Luther, Chief, Generic Animal Drug Team, at 301-827-8549, 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