DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

SP 01P-0394/CP 1

NOV 6 2001

Gene Komer, Ph.D., Consultant
2817 West County Road 54G
Fort Collins, CO 80524-1087

Dear Dr. Komer:

We refer to your Suitability Petition filed September 6, 2001, on behalf of ECO LLC, 8209 Hollister Avenue, Las Vegas, Nevada 89131, 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 Heartgard® Chewables (ivermectin) which is intended for use in dogs (NADA 140-886).

Your proposed product differs from the pioneer product in dosage form. The proposed generic product is a chewable compressed tablet, whereas the pioneer is a chewable formulation that is an "extruded" product that has a texture similar to a semi-moist dog food. The directions for use, the amount of active ingredient per dosage unit, and the dosage of active ingredient per pound of body weight will be the same.

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 submission.

In addition to a study to demonstrate bioequivalence between the pioneer and 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.

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.

01P-0394

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You may contact Dr. Lonnie W. Luther, Generic Animal Drug and Quality Control Staff, telephone (301) 827-0209, for any questions on the specific requirements for the ANADA submission.

Sincerely yours,

Claire M. Lathers, Ph.D., F.C.P.
Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine