DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

SP 06P-0093/CP 1

MAY 5 2006

ECO Animal Health
Attention: Nate Manco
Director, US Manufacturing Affairs
344 Nassau Street
Princeton, NJ 08540

Dear Mr. Manco:

We refer to your suitability petition filed March 1, 2006, in which you requested permission to submit an abbreviated new animal drug application (ANADA) for a generic product that differs from an approved new animal drug. The proposed pioneer product is Merial Ltd.'s Ivomec® (ivermectin) Injection, which is intended for use in cattle and swine (NADA 128-409). Your proposed product would contain twice the strength (concentration) of ivermectin given in a dose volume one-half that of the pioneer's product.

Your proposed product differs from the pioneer product in strength. A change in strength is one of the five variances in the pioneer product which can be sought through a suitability petition under section 512(n)(3) of the FFDCA, as amended. Pursuant to that provision, we are required to approve the petition unless we determine that investigations must be conducted to establish the safety and effectiveness of the proposed product. We conclude that your petition must be denied because investigations must be conducted to show the safety and effectiveness of your proposed product.

The increase in strength of ivermectin will necessitate evaluation of the target animal safety and effectiveness of the proposed product. Based on your request, we will require an original new animal drug application (NADA) for the proposed product.

If you disagree with our denial of your suitability petition, you may petition for reconsideration of the denial following the procedures set forth in 21 CFR 10.33. Such petition should be submitted in accordance with § 10.20 in the format outlined in § 10.33. The petition must be based solely on the information and views contained in your original petition. The petition for reconsideration should be submitted no later than 30 days after the date of this denial of the suitability petition and must be filed with the Division of Dockets Management, Food and Drug Administration, HFA-305, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please refer to docket number 06P-0093 in any submission regarding this original suitability petition.

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If there is additional information not included as part of your original submission that you would like the agency to consider, you should submit a new petition under § 10.30 and include all necessary information to the Division of Dockets Management at the address noted above.

This action in response to your suitability petition does not alter the requirements for approval of a new animal drug, nor assure approval of the new animal drug.

If you wish to discuss or have any questions, you may call Dr. Daniel A. Benz, Chief (acting), Generic Animal Drug Team, (301) 827-0169. For the requirements of a new animal drug application you may call Dr. Joan C. Gotthardt, Director, Division of Therapeutic Drugs for Food Animals, (301) 827-7571.

Sincerely yours,

Steven D. Vaughn DVM

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