DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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SP 06P-0093/PRC1

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

Re: Reconsideration of your suitability petition

Dear Mr. Manco:

We are denying your petition for reconsideration dated June 3, 2006, in which you requested that we reconsider our denial of the suitability petition you filed March 1, 2006.

Your March 1, 2006, suitability petition requested permission to submit an abbreviated new animal drug application (ANADA) for a generic copy of Merial Ltd.'s IVOMEC® (ivermectin) 1 % Injection, NADA 128-409. Your proposed generic drug product would contain twice the strength of Merial's IVOMEC® given once in a parenteral dosage form in a dose volume one-half that of Merial's ivermectin. The proposed 2% 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.

The original suitability petition was denied because of a determination that the increase in strength of ivermectin would necessitate evaluation of the target animal safety and effectiveness of the proposed product. After careful examination of your petition for reconsideration, we are denying your petition for reconsideration.

We are required to approve a suitability petition unless we determine that in addition to bioequivalence evaluations, additional investigations are needed to establish the safety and effectiveness of the differing strength. Although an in vivo bioequivalence trial can confirm product comparability in terms of systemic safety and product effectiveness, FDA has determined that the proposed increase in strength will require an injection site safety study. Specifically, ivermectin is known to be associated with injection site reactions, and we do not have safety information regarding the proposed 2% strength of ivermectin. While the amount of active ingredient administered would be the same for the two products, it is not reasonable to assume the 2% concentration of ivermectin will have the same injection site safety profile as the 1% ivermectin formulation. Our concerns regarding a potential difference in injection

2006P-0093

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site reaction are founded on the principle that unlike hydrophilic compounds that rapidly go into solution and therefore can be diluted by the interstitial fluids, lipophilic compounds such as ivermectin do not readily dissolve in the interstitial fluids. Therefore, to confirm that the 1% and 2% injectable products have equivalent injection site safety profiles, an injection site safety study is needed.

If you are interested in marketing your proposed drug, you should file an original new animal drug application. We encourage you to contact Dr. Joan Gotthardt, Director, Division of Therapeutic Drugs for Food Animals, (301) 827-7571, for any questions on the specific requirements for submitting an original new animal drug application.

Sincerely,

for

Margaret O'K. Glavin
Associate Commissioner for Regulatory Affairs