DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

SP 03P-0223/CP 1

JUL 31 2003

Mark L. Shepard, M.S.
Vice President
Shotwell & Carr, Inc.
3535 Firewheel Drive, Suite A
Flower Mound TX 75028-2628

Dear Mr. Shepard:

In your Suitability Petition filed May 23, 2003, on behalf of Richdel, Inc., you requested permission to submit an abbreviated new animal drug application (ANADA) for a generic product with dosage form different from that of an approved new animal drug. The approved product is Merial's Eqvalan® (ivermectin) Liquid, NADA 140-439, which is intended for use in horses.

Your proposed product differs from the approved product in dosage form only. The proposed generic product is an oral gel containing 1.0 % ivermectin, while the pioneer is a liquid containing 1.0 % ivermectin. The proposed generic product is intended to be administered by syringe and deliver the same incremental dose as the pioneer product.

Change in dosage form is one of the variances from the pioneer product which can be considered through a Suitability Petition under section 512(n)(3) of the Federal Food, Drug, and Cosmetic Act (the Act). 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.

You will need to demonstrate bioequivalence between the generic and approved products, which is required under section 512(n)(1)(E) of the Act. You will also need to demonstrate palatability of your proposed product. We may require such information with regard to a change in dosage form under section 512(n)(1)(D) of the Act. This information could be generated by conducting a palatability study as part of the demonstration of bioequivalence with the approved product. Before initiating any *in vivo* studies, we recommend that you submit protocols for our evaluation.

Approval of your Suitability Petition does not alter the requirements for approval of a new animal drug, or assure its approval.

We will conduct a detailed labeling review when the ANADA for the proposed generic product is submitted. Under section 512(n)(1)(F) of the Act, an ANADA must contain

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information to show that the labeling of the proposed generic product is the same as the labeling for the approved new animal drug except for changes required because of differences approved under a suitability petition, because of a different withdrawal period, or because the generic drug and the approved new animal drug are produced or distributed by different manufacturers. We have interpreted this to mean that the generic drug must be labeled for all the species and claims for which the pioneer is labeled (minus species and claims covered by patent or exclusivity protection)(Third Policy Letter dated August 2, 1989).

You may contact Dr. Lonnie W. Luther, Chief, Generic Animal Drug Team, telephone (301) 827-8549, for any questions on the specific requirements for the ANADA submission.

Sincerely yours,

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