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SP 02P-0416/CP 1

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 September 18, 2002, on behalf of Highland Vet-Pharma, LLC, you requested permission to submit an abbreviated new animal drug application (ANADA) for a generic product with dosage form and strength different from those of an approved new animal drug. The approved product is Merial's Eqvalan® (ivermectin) Paste, NADA 134-314, which is intended for use in horses.

Your proposed product differs from the approved product in dosage form and strength. The proposed generic product is a palatable, chewable bolus containing 22.75 mg ivermectin per bolus, while the pioneer is a paste containing 1.87 % ivermectin. The proposed generic product is intended to be offered by hand. The pioneer product is delivered by syringe. Each syringe contains sufficient paste to treat one 1250 lb horse. Each weight marking on the syringe is intended to deliver enough paste to treat 250 lbs of body weight. The proposed product would be packaged in a 5-bolus blister pack, sufficient to treat one 1250 lb horse. Each individual bolus would contain enough ivermectin to treat 250 lbs of body weight. Both products would deliver the same dose of 91 mcg ivermectin per pound (200 mcg/kg) body weight.

Change in dosage form and strength are two 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 (theAct). 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.

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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 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