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SP 01P-0427/CP 1

OCT 21 2002

Karen A. Sisson
4776 E. Horse Mesa Trail
Queen Creek, AZ 85242

Dear Ms. Sisson:

In your suitability petition filed September 20, 2001, 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 approved pioneer product is Merial's Eqvalan® (ivermectin) Paste 1.87%, which is intended for use in horses, including mares, yearlings and foals 6 to 8 weeks of age and older. Your proposed generic product would be a liquid administered either as a drench or as a top-dress on feed.

Your proposed product differs from the pioneer product in dosage form and strength. The pioneer product is an oral paste containing 1.87% by weight ivermectin. Your proposed product would be a liquid containing 10 mg/mL ivermectin. Your proposed product is intended to deliver 91 micrograms ivermectin per pound (200 mcg/kg) body weight, as does the pioneer.

Changes in dosage form and strength are two of the variances from the pioneer product which can be sought 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 show the safety and effectiveness of the proposed generic product.

Your petition is approved. However, we are concerned that young foals not yet accustomed to grain or solid feed may not consume an adequate amount of your proposed product when administered as a top-dress on feed. The labeling for the pioneer product specifically states that foals should be initially treated at 6 to 8 weeks of age and routine treatment repeated as appropriate.

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Thus, for each method of administration that you propose in your ANADA, you will need to demonstrate bioequivalence with the pioneer product, and, for use of your product as a top-dress on feed, you will need to provide information to demonstrate whether horses, particularly foals 6-8 weeks of age, can and will consume an adequate amount of the proposed drug when administered by feeding to get effective treatment. 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, which is required under section

512(n)(1)(E) of the Act. 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 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 Luther, Chief, Generic Animal Drug Staff (301) 827-8547, for any questions on the specific requirements for an ANADA.

Sincerely yours,

A handwritten signature in black ink that reads "Andrew J. Beaulieu". The signature is written in a cursive style with a large initial "A".

Andrew J. Beaulieu, D.V.M.
Acting Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine