DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUN 30 2000

SP 00P-1225/CP 1

Peter R. Miller DVM MS
Equi Aid Products, Inc.
1517 West Knudsen Drive
Phoenix, AZ 85027-1307

Dear Dr. Miller:

We refer to your suitability petition filed March 31, 2000, in which you requested permission to submit an abbreviated new animal drug application (ANADA) for a generic product that differs from that of an approved new animal drug in dosage form, route of administration and strength. The proposed pioneer product is Merial LTD's Eqvalan® Liquid (ivermectin) which is intended for use in horses (NADA 140-439). According to the information in your petition, your proposed product also differs from the pioneer product in Rx/OTC status, directions for drug intermediate mixing directions and administration, length of treatment and the treatment age for foals.

The suitability petition is denied.

The product you have proposed is an oral liquid containing 50 mg/mL ivermectin. You propose uses of this product as: 1) a top-dressing for feed; or 2) an oral dosage form in a grain mix administered at a rate of 200 micrograms ivermectin per kilogram body weight. The pioneer product is an oral liquid containing 10 mg/mL ivermectin to be administered by stomach tube or by drench. Although changes in dosage form, route of administration and strength are permitted changes that can be considered through a suitability petition under section 512(n)(3) of the Federal Food, Drug, and Cosmetic Act, as amended, your petition also proposes changes that are not permitted through a suitability petition.

You propose a change from a prescription to an over-the-counter product. Additionally, you propose a Type A medicated article to be used in the manufacture of dry Type C medicated feeds and/or Type B and Type C medicated liquid feeds, and propose extensive labeling changes to describe the manufacturing of Type B and C medicated feeds from the Type A medicated article. The pioneer directions for use describe administration as a single step by stomach tube or drench. Moreover, you propose mixing your proposed Type A medicated article into Type C medicated feeds that would provide for concentrations of the drug in the feed such that the dose would be administered over a period of time as the animal consumed its daily ration of feed. The pioneer is delivered essentially at once, or in a very short period of time. Finally, your proposed labeling states that "Foals should be treated initially when consistent intake of grain mix is occurring (usually between two and three months of age" [8 to 12 weeks of age]). The pioneer product labeling states that "Foals should be treated initially at 6 to 8 weeks of age and routine treatment repeated as appropriate." None of these proposed changes is a change in active

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ingredients, dosage form, route of administration or strength. Therefore, these changes are not changes that can be considered through a suitability petition under section 512(n)(3) of the act.

For these reasons, the petition is denied, and a new animal drug application (NADA) would be required for approval. 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 a petition is based solely on the information and views contained in your original petition and is submitted in accordance with § 10.20 in the format outlined in § 10.33. The petition for reconsideration is submitted no later than 30 days after the date of this denial of the suitability petition, and should be filed with the Dockets Management Branch, Food and Drug Administration, HFA-305, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please refer to the docket number cited above in any submission regarding this original suitability petition.

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 including all the necessary information, to the Dockets Management Branch at the address noted above.

We refer you to Dr. Melanie Berson, Director, Division of Therapeutic Drugs for Non-Food Animals, (301) 827-7540, for any questions you may have regarding study requirements for a new NADA.

Sincerely yours,

for Claire M. Lathers, Ph.D., F.C.P.
Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine