



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville, MD 20857

SP 00P-1486/PRC 1  
Peter R. Miller DVM, MS  
Equi Aid Products, Inc.  
1517 West Knudsen Drive  
Phoenix, AZ 85027-1307

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SEP 18 2002

Dear Dr. Miller:

In your petition for reconsideration, dated August 14, 2001, you requested re-examination of the Center for Veterinary Medicine's (Center's) decision on the suitability petition that you filed August 29, 2000. In your suitability petition, you requested permission to submit an abbreviated new animal drug application (ANADA) to provide for the use of ivermectin in a packet containing five chewables that are administered via hand-feeding, top-dressing or mixing in a small amount of feed, indicated for use in horses, including mares, yearlings, and foals 6 to 8 weeks of age and older. The proposed product differs in strength and dosage form from the pioneer product, Merial LTD's Eqvalan® Paste (NADA 134-314).

We have carefully examined your petition for reconsideration. We have concluded that the Center can determine whether foals will consume an adequate amount of your proposed drug product when administered by feeding to get effective treatment, without requiring the conduct of additional investigations to show the safety and effectiveness of the proposed drug product. Therefore, your original petition is approved.

The Center has concluded that a palatability study may be conducted to demonstrate whether horses, particularly foals 6-8 weeks of age, can and will consume an adequate amount of the proposed drug product when administered by feeding. Palatability studies may be required in an ANADA with regard to the change in dosage form under section 512(n)(1)(D) of the Federal Food, Drug, and Cosmetic Act.

Approval of the suitability petition does not alter the requirements for approval of the ANADA, or assure its approval. We recommend that you arrange a meeting with the Center to discuss your application and that you submit protocols for review before initiating any studies. Please include a copy of this letter in your generic application submission.

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

Sincerely yours,

John M. Taylor III  
Senior Associate Commissioner  
for Regulatory Affairs

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