



AUG 15 2000

. SP 00P-1342/CP 1

Robert D. Gunderson  
Phoenix Scientific, Inc.  
3915 S. 48<sup>th</sup> St. Terrace  
St. Joseph, MO 64503

8442 '00 AUG 16

Dear Mr. Gunderson:

We refer to your suitability petition filed June 15, 2000, in which you requested permission to submit an abbreviated new animal drug application (ANADA) for pyrantel pamoate paste. The proposed pioneer product is Pfizer's Strongid® Paste (pyrantel pamoate anthelmintic) which is intended for use in horses for the removal and control of mature infections of large strongyles, small strongyles, pinworms and large roundworms in horses and ponies (NADA 129-831).

Both products are dispensed from a syringe with the syringe plunger divided into dosage units. For both products, each unit on the syringe plunger dispenses 900 mg of pyrantel base as pyrantel pamoate, the recommended dose for 300 pounds of body weight. The proposed generic product delivers 3.75 grams of pyrantel base as pyrantel pamoate per 19.6 grams of paste (19.13% w/w), whereas the pioneer product delivers 3.6 grams of pyrantel base as pyrantel pamoate per 23.6 grams of paste (15.25% w/w). Although the proposed generic product represents a more concentrated dosage form, both products will deliver an equivalent amount of active drug when administered as labeled.

We conclude that the petition is approvable under the provisions of section 512(n)(3) of the Federal Food, Drug, and Cosmetic Act, as amended. Please include a copy of this letter in your generic application submission.

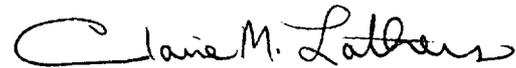
We will conduct a definitive labeling review when the ANADA for the proposed generic product is submitted to the Center. The generic labeling should be a verbatim copy of the approved labeling for the pioneer, with certain allowable differences, such as manufacturer's tradename and the changes approved in this petition.

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You may contact Dr. Lonnie W. Luther, Generic Animal Drug and Quality Assurance Staff, telephone (301) 827-0209, for any questions on the specific requirements for the ANADA submission.

Sincerely yours,

A handwritten signature in cursive script that reads "Claire M. Lathers".

Claire M. Lathers, Ph.D., F.C.P.

Director

Office of New Animal Drug Evaluation  
Center for Veterinary Medicine