



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

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SP 02P-0189/CP 1

NOV 7 2002

Robert D. Gunderson
Vice President, Regulatory Affairs
Phoenix Scientific, Inc.
3915 S. 48th St. Terrace
St Joseph, MO 64503

Dear Mr. Gunderson:

In your Suitability Petition filed April 30, 2002, you requested permission to submit an abbreviated new animal drug application (ANADA) for a generic product with a dosage form and strength different from those of an approved new animal drug. The approved product is Bayer Corporation's Droncit® (praziquantel) 34 mg Tablet, NADA 111-798, which is intended for use in dogs.

Your proposed product differs from the approved product in dosage form and strength. The proposed generic product is an oral liquid containing 68 mg/mL, while the pioneer is a tablet containing 34 mg/tablet. The generic product is intended to deliver the same dose as the pioneer product.

Changes 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 (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 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.

Approval of your Suitability Petition does not alter the requirements for approval of a new animal drug, or assure its approval.

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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

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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