



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUN 24 2004

SP 04P-0197/CP1

First Priority, Inc.
Attention: Deepak Naik
Director of Regulatory Affairs
1585 Todd Farm Drive
Elgin, IL 60123-1146

Dear Mr. Naik:

We refer to your Suitability Petition filed April 26, 2004, in which you requested permission to submit an abbreviated new animal drug application (ANADA) for a generic product with a change in strength (concentration) that differs from that of an approved new animal drug. The proposed pioneer product is Schering-Plough Animal Health's Garacin® (gentamicin sulfate) Pig Pump Oral Solution which is intended for use in swine (NADA 130-464).

The proposed generic product is intended to deliver the same amount of active ingredient per pound of body weight. Both products are designed to deliver 5 mg gentamicin sulfate per dose, in a single pump dispenser. The pioneer product delivers a volume of 1.15 mL per pump and contains a gentamicin concentration of 4.35 mg/mL. The proposed generic product will deliver a volume of 1.05 mL per pump and will contain a gentamicin concentration of 4.77 mg/mL. Although the proposed generic product represents a slightly more concentrated dosage form, both products will deliver an equivalent amount of active drug on a per dose basis.

Change in strength is one of the five variances in the pioneer product which can be considered through a Suitability Petition under section 512(n)(3) of the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended. We are required to approve the petition unless we determine that investigations must be conducted to establish the safety and effectiveness of the proposed generic product.

Your Suitability Petition is approved. Please include a copy of this letter in your generic application. Approval of the Suitability Petition does not alter the requirements for approval of the ANADA, nor assure approval of the ANADA.

If your product does not qualify for a waiver of *in vivo* bioequivalence data, you must demonstrate bioequivalence between the pioneer and the generic products. We recommend that you submit protocols for our evaluation before initiating any studies.

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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 allowed by approval of this petition.

You may contact Dr. Lonnie W. Luther, Chief, Generic Animal Drug Team, at 301-827-8549, for any questions on the specific requirements for the ANADA submission.

Sincerely yours,

A handwritten signature in black ink that reads "Steven D. Vaughn DVM". The signature is written in a cursive style with a large, stylized 'S' and 'V'.

Steven D. Vaughn, DVM
Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine