DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

SEP 06 2006

SP 06P-0263/CP1

Sparhawk Laboratories, Inc.
Attention: Bert Hughes
President / CEO
12340 Santa Fe Trail Drive
Lenexa, KS 66215-3591

Re: Suitability Petition Request

Dear Mr. Hughes:

Your suitability petition filed June 21, 2006 is approved. You requested permission to submit an abbreviated new animal drug application (ANADA) for a generic product with a change in dosage form that differs from that of an approved new animal drug. The proposed pioneer product is Pharmacia & Upjohn Co.'s Neomix® (neomycin sulfate) 325 Soluble Powder which is intended for use in cattle (excluding veal calves), swine, sheep, and goats, NADA 011-315. Approval of the Suitability Petition does not alter the requirements for approval of the ANADA, nor assure approval of the ANADA.

Your proposed product differs from the pioneer product in dosage form. The proposed generic product is an oral solution, which can be administered orally whereas the pioneer is a soluble powder. The proposed generic product is intended to deliver the same amount of active ingredient per pound of body weight, and is intended for individual animal treatment, as is the pioneer soluble powder.

Change in dosage form 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.

Please include a copy of this letter in your generic application.

In addition to an *in vivo* bioequivalence study to demonstrate bioequivalence between the pioneer and the generic products, we may require you to conduct a palatability study with the generic product. Palatability is not directly related to effectiveness.

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More than one palatability study may be necessary, depending on the method(s) of oral administration. Palatability studies may be required in an ANADA with regard to the change in dosage form under section 512(n)(1)(D) of the FFDCA. We recommend that you submit protocols for our evaluation before initiating any studies.

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.

You may contact Dr. John K. Harshman, Generic Animal Drug Team, telephone 301-827-0169, for any questions on the specific requirements for the ANADA submission.

Sincerely,

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