



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

1 3 1 7 04 MAR 25 8 1 38

SP 04P-0032/CP1

MAR 24 2004

PennField Oil Company
Attention: Gregory Bergt
Director, Research and Development
14040 Industrial Road
Omaha, NE 68144

Dear Mr. Bergt:

We refer to your Suitability Petition filed January 20, 2004, in which you requested permission to submit an abbreviated new animal drug application (ANADA) for a generic product with a change in strength that differs from that of an approved new animal drug. The proposed pioneer product is AlphaPharma's Aureo S 700[®] (chlortetracycline/sulfamethazine) Type A Medicated Article which is intended for use in beef cattle (NADA 035-805).

Your proposed product differs from the pioneer product in strength of each active ingredient from 35 g/lb to 70 g/lb; a two fold increase. The proposed generic product is intended to deliver the same amount of active ingredient per pound of body weight.

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.

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.

2004P-0032

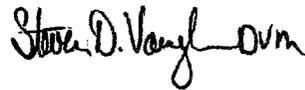
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SP 04P-0032/CP1

Page 2

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 horizontal line underlining the name.

Steven D. Vaughn, DVM

Director

Office of New Animal Drug Evaluation
Center for Veterinary Medicine