

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

0723 10 12 2002

SP 02P-0084/CP 1

Michael Strobel, DVM
Pharmaceutical Solutions, Inc
1196 S. Highway 3
Northfield, MN 55057

NOV 7 2002

Dear Dr. Strobel:

In your Suitability Petition filed February 26, 2002, you requested permission to submit an abbreviated new animal drug application (ANADA) for a generic product with dosage form, strength, and method (route) of administration that differ from those of an approved new animal drug. The approved pioneer product is Schering-Plough's Tribissen® 400 Oral Paste (trimethoprim and sulfadiazine) which is intended for use in horses (NADA 131-918).

Your proposed product differs from the pioneer product in dosage form, strength, and route of administration. The proposed generic product is a liquid suspension intended to be administered by stomach tube, whereas the approved product is a paste intended to be administered by placing it on the back of the tongue. Your proposed product will contain 56 mg trimethoprim and 280 mg sulfadiazine per gram of liquid suspension, whereas the approved product contains 67 mg trimethoprim and 333 mg of sulfadiazine per gram of paste. The recommended dose for your proposed product is 3.75 mL (4.46 g) of liquid suspension per 110 lbs (50 kg) body weight, which is equivalent to 3.75 g of the approved paste per 110 lbs (50 kg).

Changes in dosage form, strength and route of administration are three 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. 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.

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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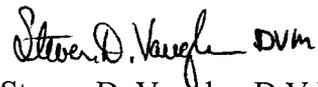
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information to show that the labeling of the proposed generic product is the same as the labeling for the approved new animal drug except for changes required because of differences approved under a suitability petition, because of a different withdrawal 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