DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUL 26 2001

SP 00P-1600/CP 1

James Damico, President
SciReg, Inc.
12733 Director's Loop
Woodbridge, VA 22192

6649 '01

Dear Mr. Damico:

We refer to your suitability petition filed November 3, 2000, on behalf of Buford Biomedical, in which you requested permission to submit an abbreviated new animal drug application (ANADA) for a generic product that differs from an approved new animal drug in strength and dosage form. The approved pioneer product referenced in your petition is Merial LTD's Eqvalan® Paste (ivermectin) which is intended for use in horses, including mares, yearlings, and foals 6 to 8 weeks of age and older (NADA 134-314).

Your proposed product differs from the pioneer product in strength and dosage form. The pioneer product is an oral paste formulated as 1.87% or 18.7 mg ivermectin per gram of paste, whereas your proposed product is a microbead (powder) formulation containing 6.8% or 68 mg ivermectin per gram and is administered via top-dressing or mixing in a small amount of feed. The dosage of active ingredient per pound of body weight will be the same.

Changes in strength and dosage form are 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. Pursuant to that provision, we are required to approve a petition for a new animal drug intended for use in a non-food animal unless we determine that investigations must be conducted to show the safety and effectiveness of the differences in the proposed generic product.

We have concluded that your suitability petition must be denied because studies must be conducted to show the effectiveness of the proposed dosage form in horses. Unlike the pioneer product, the proposed generic would be administered orally via top-dressing or mixing in a small amount of feed. We are concerned that foals may not consume an adequate amount of your proposed drug product when administered via feeding to get effective treatment.

However, you may wish to submit a hybrid application as described in our Seventh GADPTRA Policy Letter, dated March 20, 1991, which combines the elements of an ANADA and an NADA. The exact requirements of a hybrid application depend on the product for which the application is submitted and may include a bioequivalence study and any additional studies required for approval of the application. Therefore, we recommend that you arrange a meeting with us to discuss the studies we believe will be necessary and that you submit protocols for our review before initiating any in vivo studies.

00P-1600

PDNI

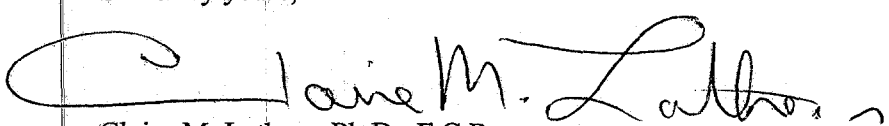
If you disagree with our denial of your suitability petition, you may petition for reconsideration of the denial following the procedures set forth in 21 CFR 10.33. Such petition should be submitted in accordance with § 10.20 in the format outlined in § 10.33. The petition must be based solely on the information and views contained in your original petition. The petition for reconsideration should be submitted no later than 30 days after the date of this denial of the suitability petition and must be filed with the Dockets Management Branch, Food and Drug Administration, HFA-305, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please refer to docket number 00P-1600 in any submission regarding this original suitability petition.

If there is additional information not included as part of your original submission that you would like the agency to consider, you should submit a new petition under § 10.30 and include all necessary information to the Dockets Management Branch at the address noted above.

This action in response to your suitability petition does not alter the requirements for approval of a new animal drug, nor assure approval of the new animal drug.

If you have any questions regarding this letter, please call Dr. Allen Rudman, Deputy Director, Office of New Animal Drug Evaluation, (301) 827-0204.

Sincerely yours,



Claire M. Lathers, Ph.D., F.C.P.
Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

NOVEMBER 03, 2000

DOCKET NUMBER: 00P-1600

TITLE: ANADA Suitability for Ivermectin
ACTION OFFICE: HFV-102

FAP/CAP/GRASP Number:

| ITEM CODE | RECEIVED MM DD YY | FILED MM DD YY | P C | SUBMITTER | FR DATE | FR PAGE | COM/OBJ MM DD YY | VOL | MISCELLANEOUS |
|---|---|---|---|---|---|---|---|---|---|
| CP1 | 11/01/00 | 11/03/00 | C | SciReg, Inc.<br>Signature: James S. Damico | | | | 1 | ACK 11/3/00 |
| ACK1 | 11/03/00 | 11/03/00 | E | HFA-305<br>Signature: Lyle D. Jaffe | | | | 1 | |

MEMO

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR VETERINARY MEDICINE

DATE: 7/26/01

FROM: Animal Scientist
Quality Assurance Support Staff, HFV-102

SUBJECT: Suitability Petition Response for Display.

TO: Lyle Jaffe, HFA-305, 5630 Fishers Lane, rm. 1061, Rockville, MD
Dockets Management Branch, 301 827-6860 (V)

01 JUL 30 AM 10:40

The attachment is the Center for Veterinary Medicine's letter related to Suitability Petition **SP 00P-1600CP 1**, submitted by SciReg, Inc., filed as a **Suitability Petition**. We are forwarding a copy for public display with the petition.

If you have any questions, please call me at 827-0211, or FAX 827-4317.

Thank you.

7-27-01

Sam Hansard, Ph.D.

Attachment

**Samuel Hansard, Ph.D.**
**FDA/CVM/ONADE/QASS/HFV-102**
**7500 Standish Place MPN II 384**
**Rockville, MD 20855**
**(301) 827-0211**
**(301)** 827-4317 **fax**
**shansard@cvm.fda.gov**