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00 P 0 '01 FEB -8 P6:14

February 2, 2001

BY FACSIMILE/CONFIRMATION COPY BY MAIL

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: 00P-1600/CP1 – Suitability Petition to file an ANDA for an ivermectin product for oral use in horses

Request to Hold Decision and Intention to File Addendum to Suitability Petition

To Whom It May Concern:

On behalf of our client, Royer Biomedical, Inc. ("Royer", formerly known as Buford Biomedical, Inc.), we request that the Center for Veterinary Medicine hold its decision on the above referenced petition (dated November 1, 2001, attached) until an addendum that Royer is preparing has been received and considered by the Center. Our intention is to submit an addendum to the Suitability Petition within the next two weeks.

If you have any questions about this notification of intent or request to hold the suitability petition decision or the Center plans to decide on the matter prior to receipt or consideration of the addendum, please contact either my colleague, Brian J. Malkin, or me at 202-737-5600.

00P-1600

LET1

Sincerely,

Frank J. Sasinowski

FJS/dng
Attachment

cc: Sam Hansard, II (HFV-102)
Center for Veterinary Medicine
Food and Drug Administration

Dr. Garfield Royer
Royer Biomedical, Inc.

Dr. Gerald Guest
Consultant to Royer Biomedical, Inc.

SciReg, Inc.

Science and Regulatory Consultants

November 1, 2000

Dockets Management Branch, HFA-305
Room 1-23
U.S. Food and Drug Administration
12420 Parklawn Drive
Rockville, MD 20857

00 NOV -1 P4:22
01070

Re: Suitability Petition to file an ANADA for an ivermectin product for oral use in horses

Dear Sir/Madam:

On behalf of Buford Biomedical, Inc., SciReg, Inc. is submitting the enclosed Suitability Petition. In the petition, Buford Biomedical requests consideration to file an Abbreviated New Animal Drug Application (ANADA) for the use of a dosage form of ivermectin that differs from the pioneer product approved under NADA 134-314 (Eqvalan Paste).

If you should have any questions regarding the enclosed materials, please contact me directly.

Sincerely,

James S. Damico
President

Enclosure

12733 Director's Loop, Woodbridge, VA 22192
Telephone: (703) 494-6500 Facsimile: (703) 492-6600
www.SciReg.com

00P-1600

CP 1

Suitability Petition

Identification of Petitioner

This petition is submitted on behalf of Buford Biomedical, Inc. (4580F Mack Avenue, Frederick, MD 21703), by SciReg, Inc. (12733 Director's Loop, Woodbridge, VA 22192) in accordance with Section 512(n)(3) of the Federal Food, Drug, and Cosmetic Act.

Action Requested

The petitioner would like to file an Abbreviated New Animal Drug Application (ANADA) for the use of a dosage form of ivermectin that differs from the pioneer product approved under NADA 134-314 (Eqvalan Paste).

Specifically, Buford Biomedical requests permission to submit an ANADA for a 6.8% ivermectin microbead (powder) formulation (i.e., 68 mg ivermectin/g powder). The product will be administered to horses orally in a small amount of feed. The pioneer product is formulated as a 1.87% (18.7 mg/g) paste that is administered directly into horses' mouths. Please note that FDA's Center for Veterinary Medicine has previously approved Suitability Petitions for very similar dosage form changes (89P-0509 and 96P-0438).

Statement of Grounds

The petitioner intends to package its product so that one bottle delivers the same amount of ivermectin as one syringe of Eqvalan Paste; that is, one bottle (1.68 g) will treat up to 1250 pounds body weight. The recommended dose rate (91μg/lb. body weight) for the pioneer product and Buford Biomedical's proposed product is identical.

Aside from changes necessitated by the different dosage form, the indications, precautionary and warning statements, and other labeling for the proposed product will be identical to the pioneer product. Enclosed please find two copies of the pioneer label; one is marked to indicate changes that will be made for Buford Biomedical's proposed product.

Both dosage forms are administered orally and the clinical effect of both is expected to be similar. In the ANADA, the petitioner intends to demonstrate bioequivalency, in horses, of the proposed dosage form relative to the pioneer product.

Environmental Impact

The action of submitting this Suitability Petition and its review by CVM is not expected to have an environmental impact. The action requested qualifies for categorical exclusion under 21 CFR, Part 25.30(h) from the requirement for an environmental assessment and, to the best of the sponsor's knowledge, no extraordinary circumstances exist.

Economic Impact

An economic impact analysis of this action will be provided upon request of the Commissioner.

Certification

I, James S. Damico, acting as Buford Biomedical's representative, have included all information known to me which is unfavorable to the petition.

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

*SciReg, Inc. is the authorized agent for Buford Biomedical, Inc.

INDICATIONS: Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. EQVALAN® (ivermectin) Paste provides effective control of the following parasites in horses. **Large Strongyles** (adults) — *Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus*, *Triodontophorus* spp. **Small Strongyles** including those resistant to some benzimidazole class compounds (adults and fourth-stage larvae) — *Cyathostomum* spp., *Cylicocyclus* spp., *Cylicostephanus* spp., *Cylicodontophorus* spp. **Pinworms** (adults and fourth-stage larvae) — *Oxyuris equi*. **Ascarids** (adults and third- and fourth-stage larvae) — *Parascaris equorum*. **Hairworms** (adults) — *Trichostrongylus axei*. **Large-mouth Stomach Worms** (adults) — *Habronema muscae*. **Bots** (oral and gastric stages) — *Gasterophilus* spp. **Lungworms** (adults and fourth-stage larvae) — *Dictyocaulus arnfieldi*. **Intestinal Threadworms** (adults) — *Strongyloides westeri*. **Summer Sores** caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae. **Dermatitis** caused by neck threadworm microfilariae, *Onchocerca* sp.

DOSAGE AND ADMINISTRATION: This syringe contains sufficient paste to treat one 250 lb horse at the recommended dose rate of 91 mcg ivermectin per kg (200 mcg/kg) body weight. Each weight marking on the syringe plunger delivers enough paste to treat 250 lb body weight.

(1) While holding plunger, turn the knurled ring on the plunger 1/4 turn to the left and slide it so the side nearest the barrel is at the prescribed weight marking. (2) Lock the ring in place by making a 1/4 turn to the right. (3) Make sure that the horse's mouth contains no feed. (4) Remove the cover from the tip of the syringe. (5) Insert the syringe tip into the horse's mouth at the space between the teeth. (6) Depress the plunger as far as it will go, depositing paste on the back of the tongue. (7) Immediately raise the horse's head for a few seconds after dosing.

PARASITE CONTROL PROGRAM: All horses should be included in a regular parasite control program with particular attention being paid to mares,

foals and yearlings. Foals should be treated in late al 6 to 8 weeks of age, and routine treatment repeated as appropriate. Consult your veterinarian for a control program to meet your specific needs. EQVALAN® (ivermectin) Paste effectively controls gastrointestinal nematodes and bots of horses. Regular treatment will reduce the chances of verminous arteritis caused by Strongylus vulgaris.

PRODUCT ADVANTAGES: Broad-spectrum Control —EQVALAN Paste kills important internal parasites, including bots and the arterial stages of S. vulgaris, with a single dose. EQVALAN Paste is a potent anti-parasitic agent that is neither a benzimidazole nor an organophosphate. Safety – EQVALAN Paste may be used in horses of all ages, including mares at any stage of pregnancy. Stallions may be treated without adversely affecting their fertility.

WARNING: Do not use in horses intended for food purposes.

CAUTION: EQVALAN (ivermectin) Paste has been formulated specifically for use in horses only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.

Refrain from smoking and eating while handling. Wash hands after use. Avoid contact with eyes. Keep this and all drugs out of the reach of children.

Ivermectin and excreted ivermectin residues may adversely affect aquatic organisms. Do not contaminate ground or surface water. Dispose of the syringe in an approved landfill or by incineration.

NOTE TO USER: Swelling and itching reactions after treatment with EQVALAN Paste have occurred in horses carrying heavy infections of neck threadworm (Onchocerca spp microfilariae). These reactions were most likely the result of microfilariae dying in large numbers. Symptomatic treatment may be advisable. Consult your veterinarian should any such reactions occur. Healing of summer sores involving excessive

tissue changes may re
appropriate therapy in
treatment with EQVAL
Paste. Reinfection and
prevention, should as
Consult your veterinarian
tion does not improve.

EACH SYRINGE CONTAINS
1.87 g IVERMECTIN PASTE

EQVALAN PASTE
MERCK & CO., INC.

U.S. Pat. 4,199,569 Made in U.S.A.

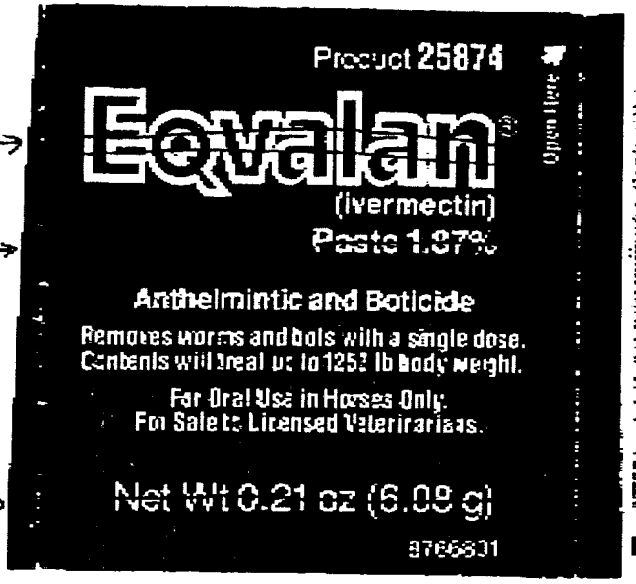
MERCK
Agvet Division

Merck & Co., Inc.
Rahway, N.J.

IVERDEX EQUINE →

Microbeads 6.5% →

Net wt 0.21 oz (6.09 g) →



IVERDEX

microbeads

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bottle

DOSAGE AND ADMINISTRATION: This ~~syringe~~ contains sufficient ~~paste~~ to treat one 1252 lb horse at the recommended dose rate of 91 mcg ivermectin per lb (200 mcg/kg) body weight. Each ~~weight-marking on the syringe plunger~~ delivers enough paste to treat 250 lb body weight.

1 2

microbeads

scoopful

Product IVERDEX label

Add appropriate amount of IVERDEX microbeads to approximately one pound of sweet feed, then provide to horse.

IVERDEX microbeads

~~(1) While holding plunger, turn the knurled ring on the plunger 1/4 turn to the left and slide it so the side nearest the barrel is at the prescribed weight marking. (2) Lock the ring in place by making a 1/4 turn to the right. (3) Make sure that the horse's mouth contains no feed. (4) Remove the cover from the tip of the syringe. (5) Insert the syringe tip into the horse's mouth at the space between the teeth. (6) Depress the plunger as far as it will go, depositing paste on the back of the tongue. (7) Immediately raise the horse's head for a few seconds after dosing.~~

PARASITE CONTROL PROGRAM: All horses should be included in a regular parasite control program with particular attention being paid to mares,

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tissue changes may r[illegible] appropriate therapy in [illegible] treatment with ~~EQVAL~~ Paste. Reinfection and [illegible] prevention should also [illegible] Consult your veterinarian [illegible] tion does not improve.

EACH ~~SYRINGE~~ bottle CONTAINS ~~6~~ 0.06 oz. IVERDEX ~~6.08 g~~ IVERMECTIN ~~PASTE~~ microbeads

~~EQVALAN ®® TM~~

~~MERCK & CO., INC.~~

~~U.S. Pat. 4,199,569~~ ~~Made in U.S.~~

MERCK ~~[illegible]~~ Buford Enterprises, Inc. 4590F Mill Pike Frederick, MD 21703

~~[illegible]~~

Frank Sussman Esq.
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