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*NOT ADMITTED IN DC

DIRECT DIAL (202) 737-4287

February 13, 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 and NADA for an Invermectin Product for Oral Use in Hourses (Iverdex ® Equine)

To Whom It May Concern:

On behalf of our client, Royer Biomedical, Inc. ("Royer", formerly known as Buford Biomedical, Inc.), we are filing the attached Letter of Clarification to the above-referenced petition (dated November 1, 2001, attached) as indicated in our February 2, 2001 letter to the file. This Letter of Clarification presents in writing information that was presented or discussed during the Royer meeting with the Center for Veterinary Medicine ("CVM") on January 25, 2001, and includes publicly available information regarding case precedent in CVM, and should not present new information requiring additional notice and comment.

If you have any questions about this Letter of Clarification, please contact my colleague, Brian J. Malkin, or me at 202-737-5600.

Sincerely,

Brian J. Malkin for
Frank J. Sasinowski

Brian J. Malkin
Brian J. Malkin

00P-1600

LET 2

FJS/BJM/tee
Enclosure

cc: Lonnie Luther (HFV-102)
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.

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Letter of Clarification to Suitability Petition 00P-1600/CP1

As stated in the original petition, Iverdex® Equine (ivermectin) is an orally administered micro-granular powdered product packaged so that one bottle delivers the same amount of ivermectin as one syringe of EQVALAN® (ivermectin) Paste. The dosage is equivalent so that one bottle of Iverdex® Equine (1.68g) will treat a horse up to 1,250 pounds body weight. The product will be packaged in order that incremental dosing of 250, 500, 750, 1,000, and 1,250 pound horses may be administered. The recommended dose rate (91 mcg/lb body weight) for the pioneer product and Royer's proposed product is identical. Iverdex® Equine is pharmaceutical-grade, and Royer plans to label, market, and distribute Iverdex® Equine as a pharmaceutical product. Iverdex® Equine is administered to the horse in a small amount of "sweet feed," but not as a "feed additive." "Sweet feed" is a commercially-available mixture of grains with molasses added. "Feed additives" are typically included with the feed and shipped as feed in large bags.

The proposed product, Iverdex® Equine, contains the same active ingredient and will be labeled with the same indications, recommended dose rates, contraindications, precautions and warnings as the approved pioneer product, EQVALAN® Paste. After oral administration of ivermectin, the gastrointestinal tract of the horse absorbs the ivermectin; therefore, it is anticipated that the bioequivalency for both drugs will be similar. The sponsor intends to provide the results of blood level testing to demonstrate the bioequivalence of the product to the EQVALAN® Paste..

Approved Paste to Powder Suitability Petitions

The Center for Veterinary Medicine ("CVM") has approved suitability petitions for a variety of other oral dosage products where the pioneer product was a paste or tablet and the generic product was a powder for feed. Examples include:

1) Petitions 89P-0509 (approved 1/24/90) & 96P-0438 (approved 1/10/97): The pioneer product was an oral paste mixture of trimethoprim and sulfadiazine, an antibacterial product indicated for horses. The generic products were powders that were administered orally, once a day, for up to five days, in a small amount of palatable feed. In the petition 89P-0509, the petitioner noted the following advantages of a powder formulation when compared to paste:

a. It allows the veterinarian to dispense an antibiotic to owners of horses who have little experience in [administering] medication.

b. It [greatly facilitates] the medication of difficult horses.

c. Large groups of horses can be medicated easily (e.g., in a "coughing or influenza" outbreak).

d. In dosing smaller horses, the correct dose can be calculated, weighed, and dispensed by the veterinarian. This is impractical with paste, where overdosing of foals, etc. can easily occur.

Suitability petition from Cheminex Labs, Inc., to Dr. Bob G. Griffiths, CVM, re: Investigational Drug 6476, at 2-3 (Nov. 28, 1989).

2) Petition 98P-1231(approved 3/3/99), 99P-4167 (approved 12/7/99), 00P-0596 (petition not required 5/5/00): Pioneer product was an oral tablet (phenylbutazone), a synthetic, non-hormonal, antipyretic compound indicated for relief of inflammatory conditions associated with the musculoskeletal system in horses. Generic products were powders or granulated powders that were administered orally, once per day, in a high dose for the first 48 hours and then gradually reduced to a maintenance dose, in a small amount of palatable feed.

Approved Deworming Agents Administered in Feed

CVM has approved a number of deworming agents that are administered in feed rather than as a syringe-delivered paste to treat parasites such as ascarids, bots, intestinal worms, lungworms, pinworms, roundworms, stomach worms, and strongyles, with the specific intended parasites varying, depending on the animal species. For example:

1) Fenbendazole is approved as a suspension, granule, paste, powder, and molasses block for use in horses, swine, goats, a variety of zoo animals, and wildlife. See 21 C.F.R. § 520.905. The instructions for the granular product states that the person administering the medication should "[s]prinkle the appropriate amount of drug on a small

amount of the usual grain ration. Prepare for each horse individually." Veterinary Pharmaceuticals and Biologicals ("VPB") at 1120 (10th ed. 1997-98).

2) Piperazine is approved as a fluid in various concentrations for use in horses. See 21 C.F.R. § 520.1802. A full dose of piperazine may be given by dose syringe or, "[i]f feed administration is preferred, give bran mash with a small amount of [piperazine] for 2 to 3 feedings, then give full dose in bran mash." VPB at 1134 (10th ed. 1997-98).

3) Pyrantel tartrate is approved as a powder or pellet for use in horses. See 21 C.F.R. § 520.2045. The powder is administered as a single dose mixed with the usual grain ration. See VPB at 1140-41 (10th ed. 1997-98).

4) Thiabendazole is approved as a top dressing, mineral protein feed block, paste, drench, bolus, and powder when mixed with trichlorfon or piperazine phosphate for use in horses, sheep and goats. See 21 C.F.R. § 520.2380. The top dressings for horses are powders that are sprinkled over food and typically are consumed at one time. See VPB at 766 (10th ed. 1997-98).

5) Tioxidazole is approved as granules or a paste for horses. See 21 C.F.R. § 520.2473. The granules are sprinkled on a small amount of the usual grain ration. The mix is prepared for each horse individually. See id.

6) Levamisole hydrochloride is approved as a bolus tablet, topical dipping agent, soluble drench powder, premix resinate, solution to mix with drinking water, and injectable, for use in cattle, swine, or sheep. See 21 C.F.R. § 520.1242. The premix resinate "resembles tiny, translucent golden beads . . . is free flowing, non-dusting and stable," and mixes uniformly with the regular feed. VPB at 1170 (10th ed. 1997-98).

Anti-Inflammatory Horse Drugs with Powder Formulations Administered in Feed

CVM has also approved a wide variety of anti-inflammatory pharmaceutical products specifically for horses that are administered with feed. Allowing the administration of this category of pharmaceuticals with feed demonstrates CVM's historic confidence in the reliability of mixing pharmaceuticals in feed as an acceptable dosage method. Examples include:

1) Meclofenamic acid, a nonsteroidal drug with anti-inflammatory, analgesic and antipyretic properties, is approved as a granular product added to the daily grain ration. See 21 C.F.R. § 520.1330. The label indicates "a moist feed, molasses added, is suggested to prevent separation of medication from the feed." VPB at 437 (10th ed. 1997-98).

2) Dexamethasone, a synthetic analogue of prednisolone, which has similar but more potent anti-inflammatory therapeutic action and diversified hormonal and metabolic effects compared to prednisolone, is approved as an intravenous or intramuscular injection; or a powder, bolus or tablet, as an anti-inflammatory agent. See 21 C.F.R. §§ 520.540, 522.540. The powder is packaged in packets containing 10 mg crystalline dexamethasone, and is indicated to be "easily administered by drench or by sprinkling on a small amount of feed." VPB at 444 (10th ed. 1997-98).

3) Flunixin meglumine, a non-narcotic, nonsteroidal, analgesic agent with anti-inflammatory and antipyretic activity, is approved as an intravenous or intramuscular injection, paste, and granular product. See 21 C.F.R. §§ 520.970, 522.970. The granular product is administered by sprinkling on a small amount of feed. See VPB at 447 (10th ed. 1997-98).

Comparison between Pioneer Drug and Proposed Product

During the January 25, 2001 meeting between Royer and CVM, Royer presented the following chart comparing Iverdex® Equine to EQVALAN® Paste:

Criteria	EQVALAN® Paste	Iverdex® Equine
Dosage (total)	113.8 mg active ingredient/pkg.	Same
Dosage (incremental)	22.8 mg/250 lb horse	Same
Target Species	Equine	Same
Route of Administration	Oral	Same
Active Ingredient	Ivermectin	Same
Dosage Form	Paste	Powder

Advantages of Iverdex® Equine Over Ivermectin Paste

Current Ivermectin Products

Ivermectin paste is an over-the-counter ("OTC") drug indicated for the treatment and control of strongyles, pinworms, stomach worms, lungworms, threadworms, and other parasites. See 21 C.F.R. § 520.1192. The other approved form for horses is as a liquid administered by stomach tube or drench. See 21 C.F.R. § 520.1195. Ivermectin is also currently available as a sustained-release bolus for cattle. See 21 C.F.R. § 520.1197; tablets and chewables for dogs and cats, see 21 C.F.R. § 520.1193; and as a drench for sheep, see 21 C.F.R. § 520.1194.

Background for Iverdex® Equine

When ivermectin paste is administered to the horse, the horse remembers the disagreeable experience associated with the ivermectin paste, the stress and rough handling of being physically restrained during the administration, and consequently the horse creates a fear response for the white syringe. Ivermectin paste has been approved as an OTC product, so most horse owners administer the paste themselves. For reasons stated above, it is sometimes difficult to give the proper dose of paste. This is especially true for fractious horses.

Iverdex® Equine was developed as a powdered form of ivermectin for ease of administration to the horse, creating a positive experience between the horse owner and the horse that facilitates proper dosing (and frequency of dosing). Most horses relish sweet feed. When administering Iverdex® Equine, the powder is mixed with sweet feed, and the horse readily eats the medicated mixture. Preliminary evaluation of Iverdex® Equine in privately owned animals showed no refusal of the product in 30 separate feedings of the proposed dose administered in sweet feed. Likewise, the same 100% consumption occurred when the product was offered on 10 occasions to experimental horses used in a preliminary egg count study.

Description of Iverdex® Equine

The raw substance, pharmaceutical-grade ivermectin, is incorporated (not encapsulated) in a Matrix III micro-granular powder formulation, making it an immediate-release powder that is both tasteless and odorless for ease of administration to the horse. The micro-granules (45-150 microns in size) appear to the naked eye as a very fine powder. The directions for use require that the person administering the Iverdex® Equine sprinkle the micro-granular powder on the sweet feed and mix thoroughly. The molasses in the sweet feed allows the Iverdex® Equine to stick to the feed grains and keeps the product from falling down to the bottom of the feed bucket.

Iverdex® Equine is mixed with the sweet feed is by hand. A full dose for a 1250 lb horse is 1.68g Iverdex® Equine (the packaging accommodates 5 incremental dosages from 250 lbs to 1250 lbs). The full dose is approximately equivalent to a thimble full of powder. The appropriate dose is added to 1 quart of sweet feed for the horse and mixed in the feed bucket. The dose readily mixes with and disappears into the sweet feed.

Unlike some of the other approved formulas that CVM has approved, Iverdex® Equine will be labeled, packaged, marketed, and distributed as a pharmaceutical product. The product will be administered on an individual bases to each horse, every 8-10 weeks, as is the pioneer product.

Brief History of Veterinary Administration of OTC Equine Deworming Products

Veterinarians are responsible for providing good preventive care to their clients' animals, as well as diagnosing and treating disease conditions. Prior to the widespread use of ivermectin deworming products, fenbendazole granules were the equine dewormer of choice, because a horse owner could obtain the product from a veterinarian, take the dose home in a plastic package, and administer it to their horses in the feed.

Initially, when the therapeutic advantages of ivermectin became known, it was administered solely as an injectable product. Since the late 1980's when the ivermectin paste became available as an OTC product, Royer estimates that the OTC portion of the ivermectin paste market now accounts for well over half (nearly 70%) of the market sales. The remainder includes approximately 23-25% of the product being dispensed by a veterinarian, but administered by a layperson. The remaining 5-7% accounts for the administration of the ivermectin by the veterinarian during a routine examination. The addition of Iverdex® Equine to the ivermectin market for horses would enhance the goal of administering a consistently safe and effective dose of ivermectin to the horse.

Conclusion

As with fenbendazole and the other examples listed above, Iverdex® Equine represents the next logical step in the administration of ivermectin; that is, from paste to a powder mixed with sweet feed. The powdered administration of ivermectin is equal to, or better than, the paste formulation due to greater handler safety, ease of dosing, security of dosing, and reliability that the full amount of ivermectin is delivered to the horse.

Attached is a copy of the pioneer EQVALAN® (ivermectin) Paste product label and the proposed draft label for Iverdex® Equine.

Merck AgVet

EQVALAN®
(IVERMECTIN)
PASTE 1.87%
Anthelmintic and Boticide
For Oral Use in Horses Only
Removes worms and bots with a single dose.

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*; Neck Threadworms (microfilariae)—*Onchocerca* sp; 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 state larvae. Dermatitis caused by neck threadworm microfilariae; *Onchocerca* sp.

Dosage and Administration: This syringe contains sufficient paste to treat one 1250 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) While holding plunger, turn the knurled ring on the plunger ¼ 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 ¼ turn to the right. (3) Make sure that 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 few seconds after dosing.

Parasite Control Program: All horses should be included in a regular parasite control program. Foals should be treated initially at 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 Paste is highly effective against gastrointestinal nematodes and bots of horses. Regular treatment will reduce the chances of verminous arteritis caused by *S. vulgaris*.

Product Advantages: Broad-spectrum Control—EQVALAN Paste kills important internal parasites, including bots and the arterial stages of *Strongylus vulgaris*, with a single dose. EQVALAN Paste is a highly active 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 when handling. Wash hands after each use. Avoid contact with eyes. **Keep this and all drugs out of the reach of children.**

Caution: Ivermectin and excreted residues may adversely affect aquatic organisms. Do not contaminate ground water or surface water. Dispose of container in 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 threadworms (*Onchocerca* sp. 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 extensive tissue changes may require other appropriate therapy in conjunction with treatment with EQVALAN Paste. Reinfection, and measures for its prevention should also be considered. Consult your veterinarian if the condition does not improve.

How Supplied: EQVALAN (ivermectin) Paste 1.87% is available in 6.08 g individual syringes. ®EQVALAN is a registered trademark of Merck & Co., Inc.

Royer Biomedical, Inc.

Iverdex® Equine
(IVERMECTIN)
POWDER 6.8%
Anthelmintic and Boticide
For Oral Use in Horses Only
Removes worms and bots with a single dose.

Indications: Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. Iverdex® Equine (ivermectin) 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-state larvae)—*Oxyuris equi*; Ascarids (adults and third- and fourth-stage larvae)—Parascaris *equorum*; Hairworms (adults)—*Trichostrongylus axei*; Large-mouth Stomach Worms (adults)—*Habronema muscae*; Neck Threadworms (microfilariae)—*Onchocerca* sp; 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 sealed vial contains sufficient powder to treat one 1250 lb horse at the recommended dose rate of 91 mcg ivermectin per lb (200 mcg/kg) body weight. Each vial contains 1.68 g Iverdex® Equine and two (2) caps. Each vial is nested in a tray containing six (6) vials with a small four-sided (250 lb, 500 lb, 750 lb, and 1000 lb dose size) measuring spoon included. Twist the cap off the vial. Remove the second cap. For horses under 1250 lbs, use the appropriate size scoop on the measuring spoon to measure out the appropriate amount of Iverdex® Equine for the weight of the horse (see diagram). Sprinkle the appropriate amount of Iverdex® Equine on 1 quart of sweet feed (molasses covered grain). Make sure that the Iverdex® Equine is thoroughly mixed with the sweet feed. Replace the cap on the vial, if any Iverdex® Equine is remaining. Dose each horse individually.

Parasite Control Program: All horses should be included in a regular parasite control program. Foals should be treated initially at 6 to 8 weeks of age, and routine treatment repeated as appropriate. Consult your veterinarian for a control program to meet your specific needs. Iverdex® Equine is highly effective against gastrointestinal nematodes and bots of horses. Regular treatment will reduce the chances of verminous arteritis caused by *S. vulgaris*.

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Caution: Ivermectin and excreted residues may adversely affect aquatic organisms. Do not contaminate ground water or surface water. Dispose of containers in approved landfill or by incineration.

Note to User: Swelling and itching reactions after treatment with Iverdex® Equine have occurred in horses carrying heavy infections of neck threadworms (*Onchocerca* sp. 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 extensive tissue changes may require other appropriate therapy in conjunction with treatment with Iverdex® Equine. Reinfection, and measures for its prevention should also be considered. Consult your veterinarian if the condition does not improve.

How Supplied: Iverdex® Equine (ivermectin) Powder 6.8% is available in 1.68g individual vials, nested in a tray containing 6 vials with a small 4-sided (250 lb, 500 lb, 750 lb, and 1000 lb dose-size measuring spoon. A full vial treats a 1250 lb horse.

Iverdex® Equine is a registered trademark of Royer Biomedical, Inc., 4580F Mack Avenue, Frederick, Maryland 21703.

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FACSIMILE TRANSMITTAL SHEET

Tel. No.: (202) 737-5600 Fax No.: (202) 737-9329

FROM:	Frank Sasinowski	**DATE:**	February 13, 2001
TO:	Dockets Management Branch (HFA-305), FDA	**FAX NO.:**	(301) 827-6870
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