

Karen A. Sisson
4776 E. Horse Mesa Trail
Queen Creek, AZ 85242

2923 '01 SEP 19 P3:10

September 13, 2001

Dockets Management Branch
HFA-305, Room 4-62
Food and Drug Administration
5600 Fisher Lane
Rockville, MD 20857

Regulatory Action: Suitability Petition to Change Dosage Form From Paste to Liquid

Pioneer Product:: Eqvalan Paste 1.87%, NADA 134-314

I am respectfully requesting approval of a suitability petition to change the dosage form of Eqvalan Paste 1.87%, NADA 134-314 from a paste to a liquid to be administered either orally or as a top dressing for feed.

I am requesting the agency permit the filing of an ANADA for a liquid equine horse wormer. The pioneer product is an equine horse wormer administered orally. I am proposing a liquid product, which can be administered either orally or as a top dressing, which would be bioequivalent to the pioneer product. The liquid product would be administered at the exact same dosage of 91 mcg of ivermectin per pound (200 mcg/kg) of body weight.

This request is based on the following. Since the paste product starts out as a liquid and then is thickened to a paste, I am simply asking to be allowed to stop the procedure at the liquid state. There are currently no other dosage forms available for ivermectin, which are offered over-the-counter. The product would be measured and administered by a syringe either orally or as a top dressing. The labeling includes complete instructions, which makes it easy to administer. The consumer needs something which is easier to administered to difficult horses at an economical price. There are approved liquid ivermectins (such as NADA 140-439) but all are to be dispensed by a veterinarian. This usually requires a horse owner to have the veterinarian examine the horse prior to prescribing the product. Recent market research shows the consumer needs an alternative method of administering ivermectin wormers. The product I am proposing can be administered as a highly palatable liquid either with a syringe or to pour over the animal's current feed. I have included a graph showing blood analysis results of the same animal being tested with the pioneer paste, my ivermectin liquid as an oral drench and as

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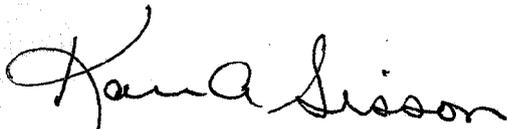
a top dressing. In the FOI for the pioneer paste on page 94, section 7, one of the agencies justifications from approving the paste was "Eqvalan (ivermectin) Paste is labeled for OTC use because the efficacy of the product covers all economically important parasites of the horse. Accordingly, the parasitic diagnosis by a veterinarian would not be required. Directions for oral administration of Evalan (ivermectin) Paste can reasonably be followed by the layman." I feel that my product is equally as easy to administer and therefore should be permitted under the same reasoning.

I have included labeling for the pioneer and the proposed product. The label for the proposed product is an exact copy of the pioneer label with proposed dosing changes in **shading**.

In anticipation of your approval of this request I am requesting a categorical exclusion under 21 CFR 25.24(a)(8) with regard to the Environmental Impact statement. An Economic Impact will be provided upon request.

I further certify that all information known to me, which may be unfavorable to the petition is included.

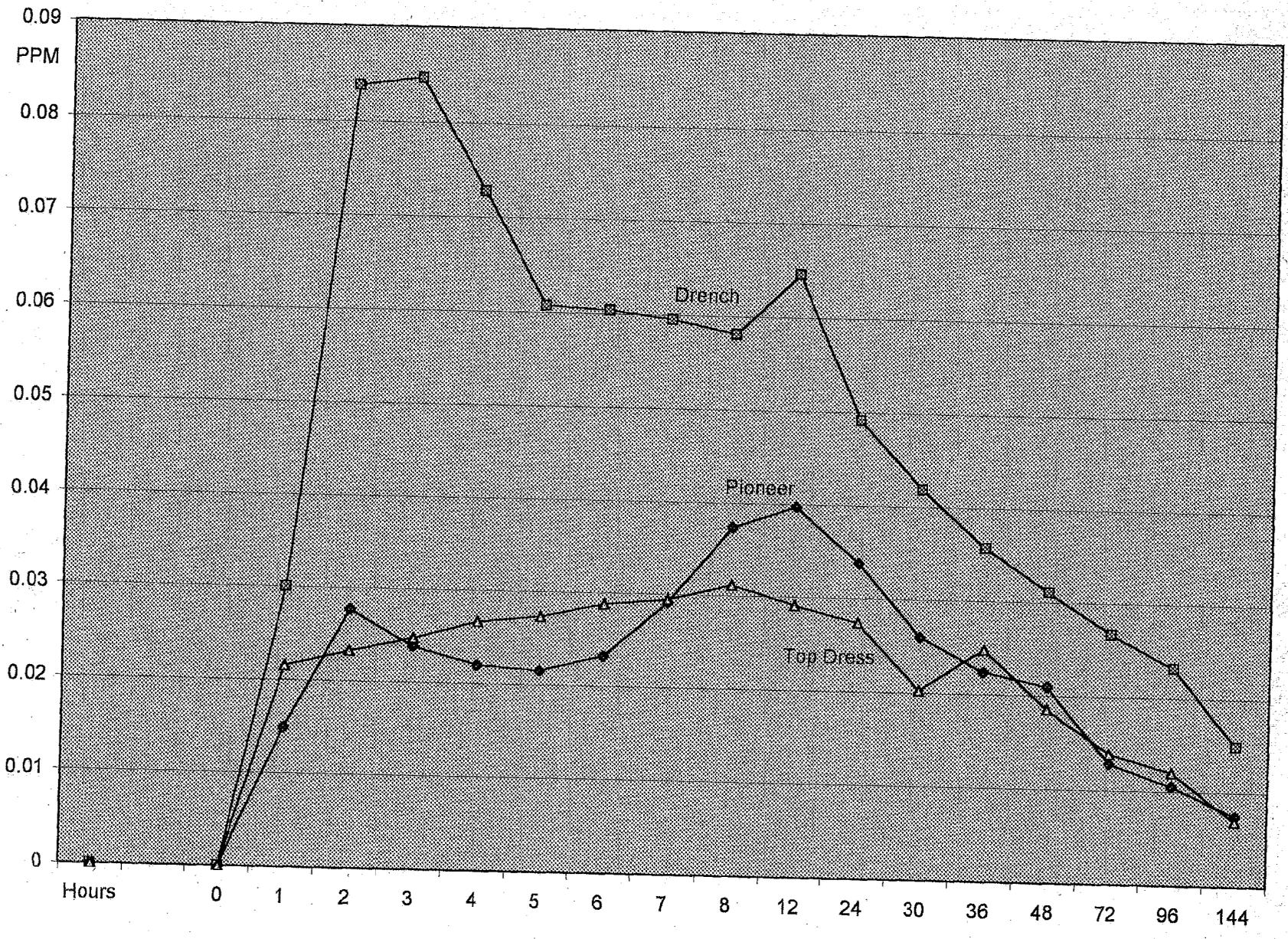
Sincerely,



Karen A. Sisson
4776 E. Horse Mesa Trail
Queen Creek, AZ 85242
480-987-8433

Enclosures:

Graph of blood results
Pioneer Label
Proposed Product Labeling



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.

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*; **Hair Worms** (adults)—*Trichostrongylus axei*; **Large-mouth Stomach Worms** (adults)—*Habronema muscae*; **Bots** (oral and gastric stages)—*Gastrophilus* spp.; **Lungworms** (adults and fourth-stage larvae)—*Dictyocaulus viverrini*; **Intestinal Threadworms** (adults)—*Strongyloides westeri*; **Summer Sores** caused by *Habronema* and *Drastrongylus* spp cutaneous third-stage larvae; Dermatitis caused by neck threadworm microfilariae, *Anchocera* sp.

DOSE 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.

Retrain from smoking and eating when 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.

(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.

PARASITIC 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 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 (ivermectin) Paste effectively controls gastrointestinal nematodes and bots caused by *Strongylus vulgaris*.

PRODUCT ADVANTAGES: Broad-spectrum Control—EQVALAN Paste kills important internal parasites, including bots and the arterial parasitic agent that is neither a benzimidazole nor an organophosphate. EQVALAN Paste is a potent anti-*Strongylus vulgaris* agent. Regular treatment will reduce the chances of verminous arteritis. EQVALAN Paste effectively controls gastrointestinal nematodes and bots.

Eqvalan®

(ivermectin) Paste 1.87%

Anthelmintic and Boticide

Net Wt 0.21 oz (6.08 g)

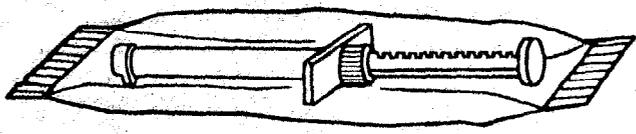
Product 25874

Removes worms and bots with a single dose.

Contents will treat up to 1250 lb body weight

For Oral Use In Horses Only

For Sale to Licensed Veterinarians



SEALED FOR SECURITY. IF BROKEN, DO NOT ACCEPT.

U.S. Pat. 4,199,569
EQVALAN and Horse Head Logo
REG TMs MERCK & CO., Inc.

Made in U.S.A.

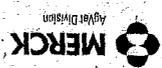
Eqvalan® 
(ivermectin) Paste 1.87%



NOTE TO USER: Swelling and itching reactions after treatment with EQVALAN (ivermectin) Paste have occurred in horses carrying heavy infections of neck threadworm (*Onchocerca* sp) microfilariae. These reactions most likely the result of microfilariae dying in large numbers. Symptoms of 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, Penicillin, and measures for its prevention should also be considered. Consult your veterinarian if the condition does not improve.

Safety — EQVALAN (ivermectin) 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.

JBK059
11-2002



Merck & Co., Inc.
Rahway, New Jersey 07065-0912, U.S.A.

Product 25874 For Oral Use in Horses Only

Eqvalan[®]
(ivermectin) Paste 1.87%

Anthelmintic and Boticide
For Treatment of Large Strongyles, Small Strongyles, Pinworms, Roundworms (Ascarids), Hairworms, Neck Threadworms, Large-mouth Stomach Worms, Bots. See carton or attached labeling for complete indications and use directions. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

NET WT 0.21 OZ (6.08 g) Made in U.S.A.

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

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

Lot No & Exp Date ▶ JBK059 11-2002



AgVet Division
Merck & Co., Inc.
Rahway, New Jersey 07065-0812, U.S.A.

8610304

Front Panel

IVERMECTIN LIQUID FOR HORSES

ANTHELMINTIC AND BOTICIDE

Removes worms and bots with a single dose

For Oral Use in Horses Only

10 mg of ivermectin per mL

Side Panels

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

Caution: 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 or eating when 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 ivermectin paste syringe in an approved landfill or by incineration.

NOTE TO USER: Swelling and itching reactions after treatment with ivermectin 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 ivermectin paste. Reinfection, and measures for its prevention, should also be considered. Consult your veterinarian if the condition does not improve.

INDICATIONS: Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. 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*, *Tridontophorus* 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** (adult and fourth-stage larvae) - *Oxyuris equi*; **Ascardis** (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) - *Gastrophilus* spp; **Lungworms** (adults and fourth-stage larvae) - *Dicryocaulus imfieldi*; **Intestinal Threadworms** (adults) - *Strongyloides westeri*; **Summer Sores** caused by *Habronema* and *Draschia* spp cutaneous third-stage larvae; **Dermatitis** cause by neck threadworm microfilariae, *Ochocerca* sp.

DOSAGE AND ADMINISTRATION: Ivermectin Liquid for Horses is formulated for administration as an oral drench or as a top dressing. The recommended dose is 200 mcg of ivermectin per kilogram (91 mcg/lb) of body weight. Each mL contains sufficient ivermectin to treat 110 lb (50 kg) of body weight.

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 as soon as a consistent intake of grain mix is occurring. This is generally between two to three months of age. Consult you veterinarian for a control program to meet your specific needs. Ivermectin top dressing effectively controls gastrointestinal nematodes and bots of horses. Regular treatment will reduce the chances of verminous arteritis caused by *S. vulgaris*.

PRODUCT ADVANTAGES: Broad-spectrum Control - Ivermectin top dressing kills important internal parasites, including bots and the arterial stages of *Strongylus vulgaris* with a single dose. Ivermectin top dressing is a potent anti-parasitic agent that is neither a benzimidazole nor an organophosphate.

Safety - Ivermectin top dressing may be used in horses of all ages, including mares at any stage of pregnancy. Stallions may be treated without adversely affecting their fertility.

Lot No. & Exp Date

ne address

Parcel register tape above the address label.

UPS
UPS Next Day Air
UPS Worldwide Express
 Shipping Document

WEIGHT	1 #	DIMENSIONAL WEIGHT	
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 The shipper certifies that these commodities, facilities or software were exported from the United States in accordance with the Export Administration Regulations. Violation contrary to U.S. law is prohibited.

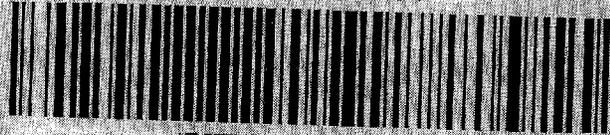
- EXPRESS (INTL)
- DOCUMENTS ONLY

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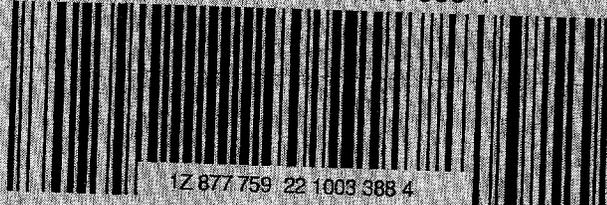


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BILL RECEIVER

UPS
UPS Next Day Air
 EXTREMELY URGENT

1Z 877 759 22 1003 388 4



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TRACKING NUMBER

DATE OF SHIPMENT

SHIPMENT ID NUMBER **8777 597B 7DW**

SHIPMENT FROM

UPS ACCOUNT NO.

8777 759

REFERENCE NUMBER

Karen A. Sisson TELEPHONE

47776 E. Horse Mesa Trail
Queen Creek, AZ 85242

DELIVERY TO

TELEPHONE

Dockers Mgmt Branch HGA-305
Food & Drug Administration
5000 Fisher Lane Rm 4-62
Rockville, MD 20857

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United Parcel Service, Louisville, KY

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DELIVERY 2