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(302) 933-4040

03 May 2005

Dr. Ken J. Harshman (HFV-104)  
C/O: Dockets Management Branch, HFV-305  
FDA/Center for Veterinary Medicine  
5630 Fishers Lane  
Rockville, Maryland 20852

**RE: SUITABILITY PETITION FOR REVIEW AND ACTION – IVERMECTIN  
SOFT CHEW FOR HORSES (JINAD 10-971)**

Dear Dr. Harshman:

Please find enclosed a suitability petition for Agency review and action. Intervet Inc. is requesting permission to file an abbreviated new animal drug application (ANADA) for a generic ivermectin soft chew that differs in dosage form, route of administration, and concentration from the pioneer product (Eqvalan<sup>®</sup> Liquid, NADA 140-439).

Your timely review of the enclosed petition will be greatly appreciated.

Please feel free to call (302-933-4040) or e-mail ([celia.shelton@intervet.com](mailto:celia.shelton@intervet.com)) me should you have any questions or if I can be of assistance.

Sincerely,

Celia B. Shelton, PhD  
Manager, Regulatory Affairs – Pharmaceuticals  
Intervet Inc.

Enclosure

Intervet Inc.  
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2005P-0170

CPI

## **Suitability Petition**

**Intervet Inc.  
Ivermectin Soft Chew Anthelmintic for Horses  
03 MAY 2005**

The undersigned submits this petition under Section 512(n)(3) of the Federal Food, Drug, and Cosmetic Act (the "Act") to request the Commissioner of Food and Drugs to permit the filing of an abbreviated new animal drug application for an oral ivermectin formulation that differs from the reference product (Eqvalan<sup>®</sup> Liquid, NADA 140-439) in dosage form, strength of the active ingredient in the proposed drug product and route of administration.

### **Action Requested**

We are requesting that the Commissioner permit the filing of an abbreviated new animal drug application for our proposed palatable ivermectin anthelmintic for horses (trade name to be determined). The abbreviated application will include a bioequivalence study. The abbreviated application will also include a consumption study, under Section 512(n)(1)(D) of the Act, to demonstrate palatability of the proposed product. Our proposed product differs from the reference product as follows:

### **Reference Product**

#### **Trade name**

Eqvalan<sup>®</sup> Liquid (NADA 140-439)

#### **Active ingredients**

Ivermectin

#### **Dosage form**

Liquid for oral administration

#### **Strength**

Each ml of Eqvalan<sup>®</sup> Liquid contains 10 mg of ivermectin (1% ivermectin)

#### **Sponsor**

Merial Limited.

#### **Dosage**

Each ml contains sufficient ivermectin to treat 110 pounds of body weight of a horse at the recommended dose of 200 mcg ivermectin/kg. Each bottle contains 100 ml of liquid sufficient to treat ten 1100 pound horses.

## Proposed Drug Product

### Trade name

To be selected

### Active ingredients

Ivermectin

### Dosage form

Palatable chewable dosage form (soft chew)

### Strength

Each soft chew contains 22.75 mg of ivermectin (0.47% ivermectin)

### Sponsor

Intervet Inc.

### Dosage

Each individual soft chew will contain 22.75 mg of ivermectin, which is sufficient to treat 250 lbs. (114 kg) of body weight at the recommended dose of 200 mcg ivermectin/kg. A blister pack will contain 5 soft chews sufficient to treat one 1250 pound horse or a bottle will contain 50 soft chews sufficient to treat ten 1250 pound horses.

## Statement of Grounds

The currently available ivermectin liquid anthelmintics require restraint of the horse to safely administer the dose as a drench or by a nasogastric tube. We propose to formulate a palatable chewable dosage form (soft chew) of ivermectin that would not require restraint of the horse to administer the dose and would be readily accepted by the horse.

The route of administration will be oral, the same as Eqvalan<sup>®</sup> Liquid, but because of the change in dosage form it cannot be administered by nasogastric tube.

The change in strength of the active ingredient is necessitated by the change in dosage form. However, the recommended dose administered per kilogram body weight for the proposed drug product remains the same as Eqvalan<sup>®</sup> Liquid, NADA 140-439 (200 mcg/kg). The soft chews will be sized so that the drug will be administered in increments to treat 250 pounds of body weight as established by the Eqvalan<sup>®</sup> Paste approval (NADA 134-314). The Freedom of Information Summary for Eqvalan<sup>®</sup> Liquid states: "The safety of ivermectin in horses has been established in trials included in previous submissions (Eqvalan paste; NADA 134-314 and Eqvalan injection; NADA 127-443)." Thus, safety studies using the 250 pound

weight increment have, in fact, been used to establish the safety of the reference product, Eqvalan<sup>®</sup> Liquid.

We are aware of objections that FDA-CVM has made to similar products regarding a concern that foals would not consume an adequate amount of the proposed drug product to get effective treatment when administered via feeding (Petition Number: 00P-1594/CP1, Highland VetPharma, LLC and Petition Number: 00P-1486/PRC1, Equi Aid Products, Inc.). We propose to address this concern with a consumption study under Section 512(n)(1)(D) of the Act.

Intervet Inc. accordingly requests approval of this suitability petition because:

- a. It is based on differences from the reference product (dosage form, strength and route of administration) that are permitted under Section 512(n)(3) of the Act;
- b. It involves only acceptable changes in labeling required by the differences in dosage form and strength or because the proposed product and reference product are produced or distributed by different manufacturers, as permitted by Section 512(n)(1)(F) of the Act; and
- c. clinical investigations are not necessary to show the safety or effectiveness of the proposed dosage form, strength, or route of administration.

#### **Environmental Impact**

Intervet Inc. requests a categorical exclusion from the requirements to file an environmental impact assessment under 21 CFR 25.33 (d) (1) as the drug is intended for use in nonfood animals.

#### **Economic Impact**

Information pertaining to the economic impact of this petition will be submitted if requested by the commissioner.

#### **Certification**

Intervet Inc. certifies that this suitability petition contains all information known to them that is unfavorable to the petition.

  
Celia B. Shelton, PhD  
Manager, Regulatory Affairs - Pharmaceuticals

03 May 2005  
Date