



000001

(302) 934-4385

03 September 2002

Dr. Lonnie Luther, Staff Chief (HFV-102)

C/O: Dockets Management Branch, HFA-305  
Room 1061  
5630 Fisher's Lane  
Food and Drug Administration  
Rockville, MD 20852

**RE: SUITABILITY PETITION FOR REVIEW AND ACTION - IVERMECTIN  
SOFT-CHEW ANTHELMINTIC FOR HORSES**

Dear Dr. Luther:

Please find enclosed a suitability petition for Agency review and action. Intervet Inc. is requesting permission to file a hybrid application as described in the Agency's seventh GADPTRA Policy Letter dated March 20, 1991. As noted in the enclosed petition, the proposed drug product (ivermectin soft-chew for horses) differs from the pioneer product, Eqvalan Paste 1.87% (NADA 134-314), in dosage form and concentration of the active ingredient.

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

Please feel free to call (302-934-4385) or e-mail ([lee.whaley@intervet.com](mailto:lee.whaley@intervet.com)) me should you have any questions or if I can be of assistance.

Sincerely,

S. Lee Whaley, MS  
Manager, Regulatory Affairs – Pharmaceuticals  
Intervet Inc.



Enclosure

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02P-0396

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**Suitability Petition**

Intervet Inc.  
**Ivermectin Soft-Chew Anthelmintic for Horses**  
**3 September 2002**

The undersigned submits this petition under Section 512 (n) (3) of the Federal Food, Drug, and Cosmetic Act to request the Commissioner of Food and Drugs to permit the filing of a hybrid application for a generic oral ivermectin formulation that differs from the pioneer product (Eqvalan<sup>®</sup> Paste NADA 134-314) in dosage form and strength of the active ingredient in the proposed drug product.

**Action Requested**

We are requesting that the Commissioner permit the filing of a hybrid application for our proposed palatable ivermectin anthelmintic for horses (trade name to be determined). The hybrid application will include bioequivalence and consumption studies. Our proposed product differs from the pioneer product as follows:

**Pioneer Product****Trade name**

Eqvalan<sup>®</sup> Paste (NADA 134-314)

**Active ingredients**

Ivermectin

**Dosage form**

Paste for oral administration

**Strength**

1.87% ivermectin

**Sponsor**

Merial Limited.

**Dosage**

One syringe contains sufficient paste to treat one 1250 lb. horse at a dosage of 200 mcg ivermectin/kg body weight. Each weight marking on the plunger delivers enough paste to treat 250 lbs. of body weight.

## Proposed Drug Product

### Trade name

To be selected

### Active ingredients

Ivermectin

### Dosage form

Palatable chewable dosage form

### Strength

0.45% ivermectin

### Sponsor

Intervet Inc.

### Dosage

Each individual treat will contain 22.7 mg of ivermectin, which is sufficient to treat 250 lbs. of body weight. Each package will contain enough palatable tablets to treat a 1250 lb. horse.

## Statement of Grounds

A palatable chewable dosage form has been selected for the proposed drug product to increase the likelihood that the horse owner will be successful in administering the required amount of the anthelmintic. The currently available ivermectin paste anthelmintics require the horse-owner to restrain the horse and force the applicator into the horse's mouth to administer the dose. After the dose is administered, the horse may still reject all or part of the dose by spitting it out. This can result in administering the wrong dose to the horse if the rejection is not observed or if excess paste is administered due to inaccurate estimation of the amount of paste rejected. To obviate these problems we propose to formulate ivermectin as a palatable chewable dosage form that could be offered to the horse and readily accepted. In this manner the horse owner can be assured that the horse received the complete dose of ivermectin.

The change in strength of the active ingredient is necessitated by the change in dosage form. However, the dose administered per kilogram body weight and the body weight intervals used to determine the amount of drug product administered would remain the same as the pioneer product. This would result in a horse of any weight receiving the same amount of ivermectin as in the pioneer product.

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 when administered via feeding to get effective treatment. We propose to address this with a consumption study.

### **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.

### **Differences Between Pioneer and Proposed Drug Product Labeling**

The changes in the labeling noted below may not be placed in the same areas as they are located on the pioneer product. The changes noted will be reflected in the proposed drug product's labeling in an appropriate manner so that it is clear and readily understood by the end-user. Please see the attached proposed labeling.

References to "Eqvalan (ivermectin) Paste" and "Eqvalan Paste" will be changed to "ivermectin" or to the new brand name as appropriate throughout the labeling.

The Eqvalan name and logo will be removed and replaced with the new brand name and logo throughout the labeling.

References to the "Paste 1.87%" will be changed to indicate that each soft-chew contains 22.7 mg of ivermectin.

The net weight of the product will be changed to reflect the net weight of the proposed drug product.

The product number will be changed.

The references to a syringe will be changed to reflect a chewable dosage form.

The patent number will be removed from the packaging.

Under Indications:

*Triodontophorus* spp. will be listed under "Small Strongyles" as this has become the practice recently.

**Under Dosage and Administration:**

The text of this section of the label will be changed to reflect the palatable chewable dosage form. The text would indicate that the package contains sufficient soft-chews to treat a 1250 pound horse at the recommended dosage rate of 91 mcg ivermectin per pound (200 mcg/kg) body weight and that each soft-chew is sufficient to treat 250 pounds of body weight.

The administration directions would indicate that the owner should administer 1 soft-chew per 250 pounds of body weight of the horse. The administration directions will indicate that the horse owner may offer the soft-chew from the hand as the soft-chews have a flavor that horses commonly find pleasing. If the owner does not wish to offer the soft-chews from the hand, the alternative method of administration would be to place the appropriate number of soft-chews on the horses feed so that they will be consumed.

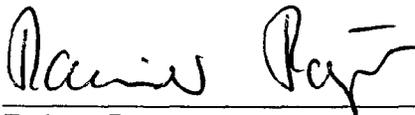
A consumption study will be done to address dosing directions for acceptance of the dosage form by various ages of horses.

**Under Parasite Control Program:**

The text referring to age of animals will be changed, if necessary, to reflect the findings of the consumption study.

**Certification**

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



Rainer Roepke, Dr. Agr.  
Director, Product Development &  
Regulatory Affairs - Pharmaceuticals

03 September 2002

Date