25 September 2003

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Eugene G. Keller
1411 S. Crestline
Spokane, WA 99203

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

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

Re: SUITABILITY PETITION for Review and Action—IVERMECTIN HARD-CHEW ANTHELMINTIC FOR (non-food) HORSES

Dear Dr. Luther:

Please find enclosed a suitability petition for Agency review and action. I, Eugene Keller, am 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 HARD-CHEW for horses) differs from the pioneer product, Eqvalan Paste 1.87%(NADA 134-314) in dosage form and concentration of the active ingredient, ingredient base, and manner of administration.

Thank you for reviewing this petition. I can be contacted at home (509-535-5037), work (509-455-9345), or by email (um1gogriz@aol.com) to answer any questions.

Sincerely,

Eugene G Keller

Eugene G. Keller, R.Ph., FACA

Enclosure

2003P-0469

CP 1

Suitability Petition
Eugene G. Keller

IVERMECTIN HARD-CHEW ANTHELMINTIC FOR HORSES

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 (Eqva!an Paste NADA 134-314) in dosage form and concentration of the active ingredient, ingredient base, and manner of administration.

Action requested

I am requesting that the Commissioner permit the filing of a hybrid application for the proposed Hard-Chew palatable version of Ivermectin which is in a base which they already readily eat, thereby simplifying the method of administering the drug to the animal. The proposed product differs from the pioneer product as follows:

	PIONEER PRODUCT	PROPOSED PRODUCT
• NAME	Eqvalan Paste(NADA 134-314)	Unnamed hard palatable treat
• Ingredient	Ivermectin	Ivermectin
• Dosage Form	Paste	Palatable Hard Biscuit
• Strength	1.87% Ivermectin	Biscuits containing 22.75mg Ivermectin
• Dose and Administration	One syringe contains sufficient paste to treat one horse up to 1250 lb. at a dosage of 200mcg ivermectin/kg body weight. Applicator must be put into animal's mouth and plunger delivers the paste dose.	Palatable hard chewable biscuits of the 22.75mg ivermectin(one per 250 lb. body weight) would be readily eaten by the animal. Biscuits would be packaged individually or in package of 5 biscuits (totaling 114mg.) to treat one horse up to 1250 lb.

STATEMENT of GROUNDS

A palatable hard chewable dosage 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 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 and with ease to the administrator.

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.

STUDIES and LABELING

Any required or necessary studies would be submitted if requested by the Commissioner. Proper labeling for the proposed drug including **ingredients** and **directions in regard to dosage and use** would be included and submitted for approval.

PERSONAL STATEMENT

As a compounding pharmacist I have already prepared this medication for a few local veterinarians on a prescription basis with very favorable feedback. The palatable biscuit has been readily welcomed as an alternative by horse and mule owners who have had difficulty getting their animal to take the paste form from a syringe. I would like to produce and package this palatable alternative as an over the counter product for the general public since ivermectin is classified as an over the counter drug.

Eugene G. Keller

Eugene G. Keller, R.Ph.,FACA

9-25-03

Date

7 October 2003

Eugene G. Keller
1411 S. Crestline
Spokane, WA 99203

Addition to : SUITABILITY PETITION—IVERMECTIN HARD-CHEW ANTHELMINTIC FOR (non-food) HORSES

ENVIRONMENTAL IMPACT

I am requesting 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. However, labeling would include warning statements that this product might be toxic to wildlife (July 31, 2003 FDA amendment to 21 CFR 522.900 effective May 2, 2003).

CERTIFICATION

I, Eugene G. Keller, certify that this suitability petition contains all information known to me which is unfavorable to this petition.

Eugene G. Keller
Eugene G. Keller
R.Ph., FACA

10-7-03
Date