

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

October 24, 2002

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 Granule/Crumble*

**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 granule/crumble to be administered alone, as a top dress, or mixed in a small amount of feed

I am requesting the agency permit the filing of an ANADA for a granule/crumble equine horse wormer. The pioneer product is an equine horse wormer administered orally. I am proposing a granule/crumbles product, which can be administered orally either alone, as a top dressing or in a small amount of feed, which would be bioequivalent to the pioneer product. The granules/crumble product is intended to deliver 91 micrograms ivermectin per pound (200 mcg/kg) body weight, as does the pioneer.

There are currently no other dosage forms available for ivermectin offered over the counter other than the paste formulation. The proposed product would be measured and administered either alone, as a top dress or in a small amount of feed in a highly palatable granule/crumble. The dosage form would be packaged in a format which would be easily measured and administered for various dosage weights. The labeling would include complete instructions allowing the consumer an easier administration method than the paste.

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 Eqvalan (ivermectin) Paste can reasonably be followed by the layman." The product I propose is at least as easy to administered and therefore should be permitted under the same reasoning.

**02P-0470**

**CP1**

Before initiating any *in vivo* studies protocols will be submitted to the agency for evaluation prior to initiating studies.

Under section 512(n)(1)(F) of the Act, the ANADA submittal will contain information to show that the labeling of the proposed generic product is the same as the labeling for the approved new animal drug except for changes required because of differences approved under a suitability petition, because of different withdrawal period, or because the generic drug and the approved new animal drug are produced or distributed by different manufacturers

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

Sincerely

A handwritten signature in black ink that reads "Karen A. Sisson". The signature is written in a cursive style with a large initial 'K' and a distinct 'S'.

Karen A. Sisson  
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Before initiating any *in vivo* studies protocols will be submitted to the agency for evaluation prior to initiating studies.

Under section 512(n)(1)(F) of the Act, the ANADA submittal will contain information to show that the labeling of the proposed generic product is the same as the labeling for the approved new animal drug except for changes required because of differences approved under a suitability petition, because of different withdrawal period, or because the generic drug and the approved new animal drug are produced or distributed by different manufacturers.

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



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