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November 3, 2003

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: ***Zimecterin® Gold (Ivermectin/Praziquantel) Oral Paste Anthelmintic for Horses***

I am respectfully requesting approval of a suitability petition to change the dosage form of Zimecterin® Gold, NADA 141-214 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 dewormer. The pioneer is an equine horse dewormer 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 bioequiavalent to the pioneer product. The granules/crumble product is intended to deliver 91 micrograms ivermectin per pound (200 mcg/kg) body weight and 454 micrograms praziquantel per pound (1.0 mg/kg of body weight, as does the pioneer.

There are currently no other dosage forms available for ivermectin/praziaquantel 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 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 Summary for the pioneer paste on under Section 5. AGENCY CONCLUSIONS – "Zimecterin® Gold Paste is labeled for OTC use. Routine deworming of horses is a widely accepted and recommended practice performed by the lay person. A diagnosis of parasite infection prior to deworming is not necessary." The

product I propose is at least as easy to administer and, therefore should be permitted to be marketed as OTC under the same reasoning as the Pioneer.

This petition is nearly identical to my previous suitability petition which was approved under SP 02P-0470/CPI, April 17, 2003. The only difference between this petition and the previously approved petition is the addition of praziquantel at an appropriate level.

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 different withdrawal periods, 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. I have included a copy of the FOI which states a 3 year marketing exclusivity and a possible patent pending. Neither of these issues can prevent my filing of this petition.

Since I have received approval of a similar petition using just ivermectin, I am anticipating your prompt review and response to this petition.

Sincerely,

Karen A. Sisson
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Enclosure: FOI – 141-214