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November 6, 2003

VIA HAND DELIVERY

Steven D. Vaughn, D.V.M.
Director
Office of New Animal Drug Evaluation
c/o Document Control Unit (HFV-199)
Center for Veterinary Medicine
Food and Drug Administration
7500 Standish Place
Rockville, MD 20855

Re: FDA Form 356V

Dear Dr. Vaughn:

Pursuant to the August 8, 2003 Notice of Opportunity for Hearing (68 Fed. Reg. 47332), we hereby submit FDA Form 356v as reconfirmation of the Agency's prior approval of NADA 141-137, a Bacitracin Methylene Disalicylate product, for the indications and use set out in 21 C.F.R. §§ 558.15(g)(1) and 558.76(d)(1) and (2). Furthermore, pursuant to this same Notice of Opportunity for Hearing, we submit FDA Form 356V as reconfirmation of the Agency's prior approval of NADA 138-939, a neomycin/oxytetracycline combination product, for the indications and use set out in 21 C.F.R. § 558.15(g)(2). We would further note that PennField Oil Company previously submitted a Form 356v to the agency for its Bacitracin Methylene Disalicylate product on November 14, 2002. Accordingly, this present submission is clearly a duplicative and unnecessary one, which is being made to merely satisfy the agency's request and to reconfirm the agency's prior approval of NADA 141-137 for all the indications of use set out in § 558.76.

Respectfully yours,

Edward John Allera

Enclosures

2003N-0324/ SUP 1

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November 6, 2003

VIA HAND DELIVERY

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. 2003N-0324: Request for Hearing Regarding NADA 138-139 (Pennfield Oil Co.)

To Whom it May Concern:

In accord with 21 C.F.R. §§ Part 12 and C.F.R. § 514.200, please find attached a full factual analysis of documents, studies, and other information supporting Pennfield Animal Health's ("Pennfield's") September 8, 2003 request for hearing with respect to neomycin/ oxytetracycline Notice of Opportunity for Hearing ("NOOH"), Docket 2003, N-0324. Due to the general notice of the NOOH and the failure of the Center for Veterinary Medicine ("CVM") to place its analysis and data on the record a filing of a specific paragraph by paragraph analysis in accord with the Agency's regulations is premature. Pennfield will continue to supplement this record and reserves the right to do so, as CVM responds with relevant documents requested by Pennfield through its Freedom of Information Act and due process requests and as CVM fulfills its disclosure obligations to ensure a complete administrative record. The following provides a concise summary of Pennfield's position regarding the Agency's approval of NADA 138-139, neomycin/oxytetracycline 2:1.

Neomycin and oxytetracycline have been marketed alone and in various combinations for use in animal feed and in other dosage forms for decades under New Animal Drug Applications ("NADAs") approved under the terms of the Federal Food, Drug, and Cosmetic Act ("FFDCA") as amended. Those combinations were reviewed as part of the Drug Efficacy Study Implementation ("DESI") Review by the National Academy of Sciences/National Research

Council and CVM. CVM finalized acceptable labeling for indications for which the combination was supported by substantial evidence of effectiveness consisting of adequate and well-controlled investigations, including field studies. Many applications and drug products either surrendered their marketing privileges, revised their labeling or had their approved applications withdrawn by the Agency. At that time the standard of effectiveness did not consider evidence of noninterference of the ingredients as critical.

In 1976, after applying this standard FDA found that neomycin and oxytetracycline in combinations with ratios of 1:1 and 2:1 were effective for all the conditions codified in 21 C.F.R. § 558.15 over the vast ranges of 0.05 mg/ head to 10 mg per head and 10 gm/ton to 500 gm per ton in poultry, swine, sheep and cattle. Pennfield's drug product is approved for all these indications for use as shown in the submission.

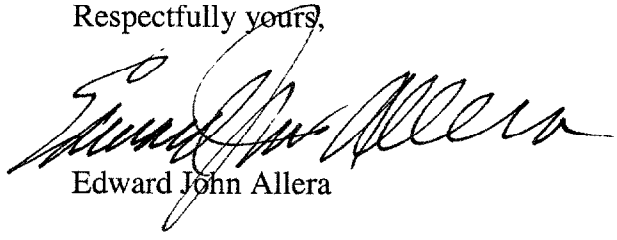
The Animal Drug Availability Act of 1996 revised the statutory standard of effectiveness to make it, in the Agency's words, more flexible and streamlined, and for combinations drugs the standard now mandates consideration of evidence of noninterference and compatibility. In this regard, once new animal drugs are found to be effective individually, they may be combined with each other as long as there is evidence of noninterference and compatibility.

The NOOH fails to address this issue, and it fails to provide any discussion about the CVM's purported review of the combination products, including the Center's reanalysis of the neo-oxy data in the 1:1 and 2:1 combination over the vast dose range and the application of the new scientific standards to the existing data and approved application. Indeed, information in the submission and evidence in the Agency's files, the long history of the drugs' usage, data in abandoned NADAs that are now publicly available, show and constitute a finding, that the combination is compatible and effective at the ratio of 1:1.

Through the application of the same standard asserted by the Center to support the effectiveness of the combination at a ratio of 1:1, the evidence indicates that the combination is effective at a ratio of 2:1. There is no evidence that the combination is less effective at a ratio of 2:1 than it is at a ratio of 1:1. This is especially true because the dosage range for the 2:1 products fall within the safe dosage range as the 1:1 products. Indeed, the information submitted also illustrates that this position is particularly relevant because the Center has asserted that the neo-oxy combination is effective in such a vast dosage range, and many, if not all of the 2:1 combination indications fall within this range. Extensive scientific evidence shows that the Agency lacks any evidence to support its position to withdraw from approval, and no evidence has been put on the public record to support the aency's position.

For all these reasons, CVM must provide the data and analysis for Pennfield to file a more precise critique of the Center's position.

Respectfully yours,



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