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Via Hand Delivery

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

Re: Request for Extension of Time and Comment Period (Docket No. 2003N-0324)

To Whom It May Concern:

REQUEST FOR EXTENSION OF TIME AND COMMENT PERIOD

The undersigned submits this petition requesting that the Commissioner of Food and Drugs stay the effective date of the following matter.

A. Decision involved

As counsel to Pennfield Oil Company/Pennfield Animal Health ("Pennfield"), we request an extension of time in which to file the supporting materials set forth in the Agency's August 8, 2003 Notice of Opportunity for Hearing ("NOOH"), Docket No. 2003N-0324.[1] On September 8, 2003 Pennfield filed with the Division of Dockets Management two requests for hearing for matters consolidated in one docket: (1) one request for NADA 141-137 (Pennitracin MD 50-G, a bacitracin methylene disalicylate ("BMD") product), and (2) one request for NADA 138-939 (NEO-OXY, a neomycin ("neo")/oxytetracycline ("oxy") combination product). The NOOH indicates that by October 7, 2003, those parties requesting a hearing should "[s]ubmit all data and analysis upon which a request for hearing relies." Finally, the NOOH states that supplemental New Animal Drug Applications ("NADAs") are to be submitted by November 6, 2003.[2] The proposed rule that is part of the same Docket No. 2003N-0324, "New Animal Drugs; Removal of Obsolete and Redundant Regulations," requests the submission of written comments by November 6, 2003.[3]

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[1] 68 FR 47332 (August 8, 2003).
[2] 68 FR 47332, 47333 (August 8, 2003).
[3] 68 FR 47272, 47272 (August 8, 2003).

B. Action requested

Pennfield requests that the company be provided with sixty (60) additional days beyond the October 7, 2003 deadline to submit its data and analysis, that is, until December 8, 2003. Pennfield also requests ninety (90) additional days beyond the October 7, 2003 deadline to submit the supplemental New Animal Drug Applications ("NADAs") called for in the NOOH, that is, until January 5, 2004. These requested time extensions will preserve the thirty (30) day time difference between submission of data and analysis, and submission of supplemental NADAs, that is set forth in the NOOH. In light of this request for extension of time to file data and analysis, Pennfield also requests that the comment period for the proposed rule, "New Animal Drugs; Removal of Obsolete and Redundant Regulations," also part of Docket No. 2003N-0324, be extended sixty (60) additional days beyond the current November 6, 2003 deadline set forth in the NOOH, that is, until January 5, 2004. This change would preserve the identical deadlines for submission of supplemental NADAs and comments on the proposed rule that were cited in the NOOH.

C. Statement of Grounds

As our requests for hearing set forth, both Pennfield and the Agency will be required to present information and arguments regarding many complex new animal drug historical issues, including the Drug Efficacy Study Implementation ("DESI") review process, the promulgation of 21 CFR § 558.15, the Generic Animal Drug and Patent Term Restoration Act ("GADPTRA"), and the resulting nine policy letters issued by the Center for Veterinary Medicine ("CVM"). In addition, because of the complexity of the approval process for both BMD and NEO-OXY, extensive data and Pennfield/Agency communication will have to be provided as well. Furthermore, Docket No. 2003N-0324, the docket for the NOOH at issue, also contains a proposed rule to remove obsolete and redundant regulations.[4] Because this docket contains two notices that contain intricately interrelated issues, the information Pennfield will need to submit in order to fully set forth its position will be extensive.

Pennfield believes that it would not only be in our best interests to put together a cohesive and well-documented package for submission to the Agency, but it would be in FDA's best interests to want to receive such a comprehensive package from Pennfield, rather than a fragmented set of information that has to be supplemented at a later date. Such a disjointed approach would waste time and valuable resources for all parties involved.

Furthermore, no one could have predicted the recent hurricane that severely affected routine business operations in the Washington D.C. metropolitan area. The federal government was closed for two days, as were our offices. The severity of the situation effectively delayed, for several days, our work on this matter. Therefore, for this additional

[4] 68 FR 47272 (August 8, 2003).

reason, we believe that justice would be served if the Agency granted our request for extension of time in this matter.

Given the fact that the drugs at issue have been approved for use for many years, there is no apparent rush to resolve this matter immediately, when such action could impede the ability of both Pennfield and FDA to make their arguments based on a fully-developed and well-documented package of data and other information.

We thank you for your consideration, and we request that you provide us with your decision on this matter as expeditiously as possible.

Respectfully yours,

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