DEPARTMENT OF HEALTH & HUMAN SERVICES

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Docket

Food and Drug Administration
Rockville MD 20857

6523 '03 OCT -3 P12:26

October 3, 2003

Mr. Edward J. Allera
Buchanan Ingersoll
1776 K Street N.W.
Washington, D.C. 20006-2365

RE: Request for Extension of Time and Comment Period
Docket No. 03N-0324

Dear Mr. Allera,

On September 26, 2003, on behalf of Pennfield Oil Company/Pennfield Animal Health (Pennfield), you requested a 60-day extension of time in which to submit (1) comments for the Food and Drug Administration's (FDA) Notice of Proposed Rulemaking (NPRM) to Remove Obsolete and Redundant Regulations; (2) supplemental New Animal Drug Applications (NADAs) for the Center for Veterinary Medicine's (CVM) Notice of Opportunity for Hearing (NOOH); and (3) data and analysis for the same NOOH. Both notices are part of Docket No. 03N-0324.

You state that your requests for extensions of time are due to the need to address many complex new animal drug historical issues, the complexity of the approval process for the two Pennfield products subject to the NOOH, the NOOH and NPRM containing intricately interrelated issues, that you will need to submit extensive information, and recent severe weather in the Washington, D.C., area.

With respect to the proposed rule, CVM has forwarded this portion of your request to the Assistant Commissioner for Policy for decision.

I am denying your extension request relating to the submission of a supplemental NADA since I disagree that the 90 days provided by the NOOH is not adequate. As stated in the Notice, the supplement must consist of a signed Form FDA 356v New Animal Drug Application and complete product labeling (including specimen labeling for Type B and Type C medicated feeds) conforming to the applicable findings of effectiveness. Your extension request does not explain why you would need an additional 60 days to provide this information, which should be readily available.

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I am extending the period of time for submitting supporting materials for hearing requests. CVM will publish a Federal Register notice extending this deadline by 30 days from the date the notice publishes. While this is less than the additional 60 days you requested, it is an increase of about 50 percent over the 60 days typically provided for NOOHs under the Drug Efficacy Study Implementation (DESI) program. *See, for example*, 68 FR 17953 (April 14, 2003) and 64 FR 14451 (March 25, 1999).

Sincerely,

Stephen F. Sundlof, D.V.M., Ph.D.
Director, Center for Veterinary Medicine

✓cc:
Docket No. 03N-0324
Division of Dockets Management (HFA-305)
Food and Drug Administration
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