



October 28, 2003

Edward J. Allera  
Buchanan Ingersoll  
1776 K Street N.W., Suite 800  
Washington, D.C. 20006-2365

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. CVM forwarded the portion of your request relating to the notice of proposed rulemaking to my office for a decision.

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.

I am denying your request to extend the comment period for the NPRM to Remove Obsolete and Redundant Regulations. FDA is already providing a 90-day comment period for the NPRM, which is a third longer than the normal 60-day period, as provided in 21 CFR 10.40(b)(2). Moreover, the NPRM involves a proposal to remove regulations on the grounds that they are obsolete, which is a much simpler action than a proposal to issue or change regulations that relies on difficult factual or policy issues. Your request thus fails to establish that comments could not feasibly be submitted within the comment period, that

your clients are anticipating that important new information will be available shortly, or that a sound public policy supports extending the comment period from 90 days to 150 days. *See* 21 CFR 10.40(b)(3)(i).

Sincerely,

A handwritten signature in black ink, appearing to read "Jeffrey Shuren". The signature is fluid and cursive, with a prominent loop at the end.

Jeffrey Shuren, M.D., J.D.  
Assistant Commissioner for Policy

Page 3 – Mr. E.J. Allera

Docket No. 03N-0324  
Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, rm. 1061  
Rockville, MD 20852

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Drafter: TForfa, HFA-305, 10/23/03

Edited: DTucker, HF-40, 10/24/03

Edited: JLocke, HF-40, 10/27/03

**Tucker, Doris**

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**From:** Forfa, Tracey  
**Sent:** Friday, October 24, 2003 9:44 AM  
**To:** Tucker, Doris  
**Cc:** Locke, Joanne; Beck, Cathy; Beaulieu, Andrew J  
**Subject:** FW: Letter for Jeff Shuren signature

Hi Doris - As discussed, I am sending you, separately a string of e-mails in which Jeff Shuren asks that OES coordinate a response to Pennfield's attorney, denying a request for an extension of the comment period for the proposed removal of 558.15.

Here are the draft responses. Please let us know if you need any additional help from us. Thanks!!! Tracey

-----Original Message-----

**From:** Beaulieu, Andrew J  
**Sent:** Friday, October 24, 2003 8:13 AM  
**To:** Beck, Cathy; Forfa, Tracey  
**Subject:** Letter for Jeff Shuren signature

The forwarded documents support the need for Mr. Shuren to send a letter to Pennfield (through their attorney) denying an extension of the comment period for the proposed removal of 558.15. The Center has already sent a letter, denying in one case and partially granting an extension in another, regarding to two notices that accompanied the proposed removal. We sent a draft of the letter we need from Mr. Shuren to him earlier, but he requests that it come to him in final through Exec. Sec. That letter, as well as the one CVM previously sent (both prepared by David Mednick), are attached for your use. David also suggests that his previous e-mail may provide useful language for the transmittal to Jeff. The comment period expires on Nov. 6, so we need to have the letter issued before that date.           AJB

10/24/2003