



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 25 2007

Food and Drug Administration  
Rockville MD 20857

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Gary L. Yingling, Esq.  
Kirkpatrick & Lockhart Preston Gates Ellis, LLP  
1601 K Street, N.W.  
Washington, D.C. 20006-1600

Re: Docket No. 2006P-0491/CP1

Dear Mr. Yingling:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received December 1, 2006. In the petition you request that the FDA make a determination that the withdrawal of Psorcon E (diflorasone diacetate) Emollient Ointment, 0.05%, was not for reasons of safety or effectiveness.

FDA has been unable to reach a decision on your petition because of the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Jane A. Axelrad  
Associate Director for Policy  
Center for Drug Evaluation and Research

2006P-0491

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