



JUN 14 2005

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Kim D. Lamon, M.D., Ph.D.  
Greg J. Kricorian, M.D.  
Valeant Pharmaceuticals International  
3300 Hyland Avenue  
Costa Mesa, CA 92626

Re: Docket No. 2004P-0557/CP1

Dear Dr. Lamon and Dr. Kricorian:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition submitted on December 21, 2004. Your petition requests that the Agency refrain from approving any abbreviated new drug application submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) for a generic version of Efudex Cream, unless the application contains data from an adequately designed comparative clinical study conducted in patients with superficial basal cell carcinoma.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. 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

2004P-0557

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