



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

December 21, 2004

FILE COPY

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

Dear Dr. Lamon and Dr. Kricorian:

Your petition requesting the Food and Drug Administration to refrain from approving any ANDA submitted for a generic version of Efudex Cream, was received by this office on 12/21/2004. It was assigned docket number 2004P-0557/CP1 and it was filed on 12/21/2004. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe
Division of Dockets Management
Office of Management Programs
Office of Management

2004P-0557

ACK1