



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

September 25, 2006

FILE COPY

Greg J. Kricorian, M.D.
Valeant Pharmaceuticals International
International Headquarters
3300 Hyland Avenue
Costa Mesa, California 92626

Dear Dr. Kricorian:

Your petition requesting the Food and Drug Administration to refrain from approving any ANDA for a diazepam rectal gel that relies on Diastat 5 mg/mL, 10 mg/mL, 15 mg/3 mL, or 20 mg/4 mL, was received by this office on 09/22/2006. It was assigned docket number 2006P-0392/CP 1 and it was filed on 09/22/2006. 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,

Gloria Ortega, Deputy Director
Division of Dockets Management
Office of Management Programs
Office of Management

2006P-0392

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