



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

FILE COPY

May 16, 2006

Joan Janulis
Lachman Consultant Services, Inc.
1600 Stewart Avenue
Westbury, New York 11590

Dear Ms. Janulis:

Your petition requesting the Food and Drug Administration to determine whether Diastat (diazepam rectal gel), 5 mg/mL, 10 mg/2 mL, 15 mg/3 mL, and 20 mg/4 mL have been voluntarily withdrawn from sale for reasons related to safety or efficacy was received by this office on 05/16/2006. It was assigned docket number 2006P-0209/CP 1 and it was filed on 05/16/2006. 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-0209

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