



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

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Joan Janulis  
Director  
Lachman Consultant Services, Inc.  
1600 Stewart Avenue  
Westbury, NY 11590

Re: Docket No. 2006P-0209/CP1

Dear Ms. Janulis:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition dated May 15, 2006. Your petition requests that FDA determine whether Diastat (diazepam rectal gel), 5 milligrams (mg)/milliliter (mL), 10 mg/2 mL, 15 mg/3 mL, and 20 mg/4 mL (NDA 20-648 held by Valeant Pharmaceuticals) was withdrawn from sale for reasons of safety or effectiveness.

FDA has been unable to reach a decision on your request 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 yours,

*Nancy E. Booker*  
for Jane A. Axelrad  
Associate Director for Policy  
Center for Drug Evaluation and Research

2006P-0209

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