DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAR 20 2007

Rec'd 3/22/07 JB

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

Re: Docket No. 2006P-0392/CP1

Dear 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 received on September 22, 2006. Your petition requests that FDA refrain from approving any abbreviated new drug application (ANDA) for a diazepam rectal gel that relies on a discontinued version of Diastat in fixed-dose syringes of 5 mg/mL, 10 mg/2 mL, 15 mg/3 mL, or 20 mg/4 mL as the reference listed drug. You maintain that if FDA permits reference to these fixed-dose drug products, the agency should require an application pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act because you claim that significant changes in labeling would be necessary for the safe use of the products.

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,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2006P-0392

LET 1