DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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SEP 25 2001

Marcy Macdonald
Associate Director, Regulatory Affairs
Apotex Corporation
50 Lakeview Parkway
Suite127
Vernon Hills, Illinois 60061

Docket No. 01P-0152/CP1

Dear Ms. Macdonald:

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 March 26, 2001, asking FDA to determine that the three-day titration dosing schedule for Neurontin capsules was not withdrawn from the labeling for reasons of safety or effectiveness, that the omission of this dosing schedule from the labeling of a generic version of Neurontin would not render the generic less safe or effective than Neurontin, and that TorPharm's abbreviated new drug application (ANDA) for a generic Neurontin may use the discontinued dosage schedule in its labeling.

FDA has been unable to reach a decision on your petition because it raises significant issues requiring extensive review and analysis by Agency officials. 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,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

01P-0152

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