



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

NOV 5 2004

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Keith Altman  
Director of Adverse Event Analyses  
Finkelstein and Partners  
436 Robinson Avenue  
Newburgh, NY 12550

Re: Docket No. 2004P-0235/CP1

Dear Mr. Altman:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your petition dated May 17, 2004, requesting that FDA require that the labeling of Neurontin (gabapentin) be revised to include certain statements about suicide-related adverse events.

FDA has been unable to reach a decision on your petition because it raises issues that require additional review and analysis by the Agency. 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,

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

2004P-0235

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