



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUL 18 2006

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Ms. Maya F. Perrott
111 Franklyn Avenue
Indialantic, FL 32903

Re: Docket No. 2006P-0251

Dear Ms. Perrott:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in the citizen petition that you submitted requesting that Depakote be withdrawn from the market or its labeling revised. Your initial submission was received by FDA on December 20, 2005. That submission, however, was incomplete as it did not contain an Environmental Impact Statement (EIS) as required by 21 C.F.R. 10.30(a). On June 15, 2006, your EIS was received, and your petition became complete.

FDA has been unable to reach a decision on your petition 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 possible given the numerous demands on the Agency's resources.

Sincerely,

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

2006P-0251

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