DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

SEP 2 0 2006

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

Re: Docket No. 2006P-0251/CP1

Dear Ms. Perrott:

I am writing to inform you that the Food and Drug Administration (FDA) is denying the citizen petition that you submitted requesting that Depakote be withdrawn from the market or its labeling revised because, unfortunately, your petition does not contain sufficient information about the adverse event that you believe you experienced as a result of Depakote use. Indeed, the information you have provided us concerning your experience is limited to the following three sentences:

> [T]he drug caused an extreme adverse reaction. I suffered a lot, and it [Depakote] caused a lot of stress in my life; financially and emotionally. I was 29 years old and had been in good physical and mental health, prior.

Without more, there is simply no way for us to evaluate whether the adverse reaction that you believe you experienced as a result of Depakote use justifies any action with regard to Depakote and, therefore, we are denying your petition.

It is important to note that all drugs have risks and benefits and the risks of serious adverse reactions are already identified in the approved labeling for Depakote. For instance, Depakote's labeling specifically identifies the risks of hepatotoxicity (liver damage), pancreatitis (inflammation of the pancreas), and thrombocytopenia (low platelet levels in the blood), among others, that may result from the use of Depakote. In addition, FDA continues to monitor the risks and benefits of all currently marketed drugs through annual reports, literature reviews, and reviews of spontaneous adverse event reports (see e.g., 21 CFR 314.80 and 314.81).

We do appreciate your willingness to share your concerns with FDA and wish to inform you that you or your healthcare provider may want to submit more detailed information about your adverse event to the Agency's safety information and adverse event reporting program, MedWatch. MedWatch allows healthcare professionals and consumers to report serious problems that they suspect are associated with the drugs they prescribe, dispense, or use, and allows for on-line reporting. If you, or your healthcare provider, are

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interested in making such a report, please visit the MedWatch Web site at http://www.fda.gov/medwatch/What.htm for detailed instructions about how to do so.

I thank you again for taking the time to share your concerns with FDA.

Sincerely,

Steven K. Galson, M.D., M.P.H.
Director
Center for Drug Evaluation and Research