DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

IND 30,673

JAN 20 [illegible]

JAN 15 1998

Abbott Laboratories
Pharmaceutical Products Division
Attention: REDACTED
100 Abbott Park Road
REDACTED
Abbott Park, IL 60064-3500

Dear Mr. REDAC:

Reference is made to your Investigational New Drug Application (IND) for Depakote[R] (divalproex sodium delayed release tablets) for bipolar disease, and your submission dated November 18, 1997.

We also refer to our January 28, 1997, letter in response to your December 10, 1996, amendment.

We have completed our review of your protocol for Study M97-738, "A Double-Blind, Placebo-Controlled Study of Depakote in the Treatment of Signs and Symptoms of Mania in Elderly Patients with Dementia", and have the following comments:

> We note that you have incorporated our recommendations regarding study design, outlined in our January 28, 1997, letter. As noted in that letter, a positive outcome for Study M97-738 could be incorporated in some way in the labeling for Depakote. We would view such an outcome more as support for a general antimanic claim, rather than as support for an expansion of the antimanic claim. The precise labeling changes that may be permitted will need to await the completion of your study and the submission of the results in a supplement.

If you should have any questions regarding these comments, please contact REDACTED REDACTED, R.Ph., Project Manager, at (301) REDACTED

Sincerely yours,

REDACTED

REDACTED, M.D.
Director
Division of Neuropharmacological
Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research