

NDA 16-508

AF 25-403

Geigy Pharmaceuticals
Division of Geigy Chemical Corp.
P.O. Box 430
Yonkers, New York 10702

MAR 11 1968

Attention: Dr. Edward C. McKen

Gentlemen:

This acknowledges the receipt on February 20, 1968 of your communication dated February 19, 1968 enclosing printed labeling pursuant to your new drug application for "Tegretol (carbamazepine) Tablets."

We also acknowledge receipt of your additional communication dated February 9, 1968.

The application was filed on February 20, 1968.

We have completed the review of this application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved.

The enclosures summarize the conditions relating to the approval of this application.

Please submit two market packages of the drug when available.

Sincerely yours,

Herbert L. Ley, Jr., M.D.
Director
Bureau of Medicine