DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-505

DEC 24 1996

The R.W. Johnson
Pharmaceutical Research Institute
Attention: Michael H. Kaufman
Assistant Director Regulatory Affairs
P.O. Box 300
Raritan, New Jersey 08869-0602

Dear Mr. Kaufman:

Please refer to your August 18, 1994 new drug application (and your resubmission dated December 29, 1994) and to your amendment dated June 27, 1996 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Topamax (topiramate) 25mg., 100mg., 200mg., round tablets

We also refer to the following amendments and correspondence:

October 3, 1995	October 4, 1995	October 5, 1995	October 9, 1995
October 10, 1995	October 17, 1996	October 19, 1995	October 25, 1995
October 30, 1995	November 8, 1995	November 20, 1995	November 27, 1995
November 30, 1996	January 3, 1996	January 17, 1996	February 9, 1996
February 22, 1996	March 15, 1996	March 29, 1996	April 5, 1996
April 22, 1996	June 18, 1996	July 3, 1996	July 11, 1996
July 25, 1996	August 6, 1996	August 9, 1996	September 20, 1996
September 26, 1996	October 9, 1996	November 7, 1996	November 22, 1996
November 26, 1996			

We have completed the review of this application, including the submitted draft labeling. Based upon our review of the reports submitted, we conclude that the NDA may be approved under labeling that allows for the use of topiramate as an adjunctive treatment for partial onset seizures in adults.

Accordingly, the application is approved as of the date of this letter provided that Topamax™ is marketed under the labeling that accompanies (attachment 1) this letter.

The final printed labeling (FPL) must be identical to the enclosed final draft labeling (Attachment 1). Marketing the product with FPL that is not identical to this draft labeling may render the product misbranded and an unapproved new drug.

Please submit sixteen copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy weight paper or similar material. For administrative purposes this submission should be designated "FINAL PRINTED LABELING" for approved NDA 20-505. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

In addition, please submit three copies of the introductory promotional material that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to the Division of Neuropharmacological Drug Products and two copies of both the promotional material and the package insert directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising and Communications, HFD-40
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact Jacqueline Ware, Pharm.D., Regulatory Management Officer at (301) 594-5526.

Sincerely yours,

Robert Temple, M.D.
Director
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE