DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug
Administration
Rockville MD 20857

NDA 20-505/S-002
NDA 20-844/S-010

R.W. Johnson Pharmaceutical Research Institute
Attention: Michael H. Kaufman
Director, Regulatory Affairs
920 Route 202 South
P.O. Box 300
Raritan, New Jersey 08869-0602

Dear Mr. Kaufman:

Please refer to the following supplemental new drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Topamax (topiramate) Tablets and Topamax (topiramate capsules) Sprinkle Capsules:

	NDA 20-505/S-002	NDA 20-844/S-010
Initial Submission:	July 31, 1997	June 7, 2001
Complete Response to Action Letter:	June 7, 2001	Not applicable
User Fee Due Date:	December 8, 2001	April 8, 2002

We also acknowledge receipt of your submissions dated July 9, 2001, July 26, 2001, August 3, 2001, and August 21, 2001 to both of these applications.

These supplemental new drug applications provide for the use of Topamax (topiramate) Tablets, Topamax (topiramate) Sprinkle Capsule as adjunctive therapy in patients 2 years and older with seizures associated with Lennox-Gastaut syndrome.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

Labeling
The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert). Please note that the enclosed labeling includes the changes in WARNINGS and PRECAUTIONS/Information for Patients sections pertaining to acute myopia and secondary angle closure glaucoma as agreed to in your August 21, 2001 amendments.

Please submit the copies of final printed labeling (FPL) electronically to each application according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no 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, these submissions should be designated "FPL for approved supplement NDA 20-505/S-002, 20-844/S-010." Approval of these submissions by FDA is not required before the labeling is used.

Promotional Material

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

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Health Care Professional Letter

As we agreed, you will send a "Dear Health Care Professional" letter informing health care professionals about the labeling changes pertaining to acute myopia and secondary angle closure glaucoma. When the letter is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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, call Jacqueline H. Ware, Pharm.D., Regulatory Management Officer, at (301) 594-5533.

Sincerely,

{See appended electronic signature page}

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

Enclosure