DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-505 S-010/S-017/S-019
NDA 20-844 S-006/S-014/S-016

Ortho-McNeil Pharmaceutical, Inc.
c/o Johnson & Johnson Pharmaceutical Research & Development, L.L.C.
Attention: Catherine M. Glamkowski
Associate Director, Regulatory Affairs
920 Route 202 South; P.O. Box 300
Raritan, New Jersey 08869-0602

Dear Ms. Glamkowski:

Please refer to your supplemental new drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Application	Drug Product	Submitted on:	Received on:	Provides for:
NDA 20-505/S-010	Topamax (topiramate) Tablets	December 13, 1999	December 14, 1999	
NDA 20-844/S-006	Topamax (topiramate capsules) Sprinkle Capsules			
NDA 20-505/S-017	Topamax (topiramate) Tablets	June 28, 2002	July 1, 2002	A change in the recommended daily dose of topiramate and an update to the relevant clinical/safety sections of labeling based on results of the TOPMAT-EPAJ-119 study.
NDA 20-844/S-014	Topamax (topiramate capsules) Sprinkle Capsules			
NDA 20-505/S-019	Topamax (topiramate) Tablets	December 10, 2003	December 11, 2003	The addition of information to certain sections of the TOPAMAX Package Insert regarding metabolic acidosis.
NDA 20-844/S-016	Topamax (topiramate capsules) Sprinkle Capsules			

We also acknowledge receipt of the following additional submissions to:

NDA 20-505/S-010 & NDA 20-844/ S-006	NDA 20-505/S-017 & NDA 20-844/ S-014	NDA 20-505/S-019 & NDA 20-844/ S-016
May 16, 2003	October 10, 2003; October 15, 2003 December 8, 2003	October 3, 2003; October 10, 2003; October 15, 2003; November 11, 2003; November 14, 2003; December 8, 2003

Your submissions of May 16, 2003 and October 15, 2003 constituted complete responses to our action letters dated December 12, 2002 and October 3, 2003.

We have completed our review of these applications, as amended. Accordingly, these applications are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

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 submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplements NDA 20-505 S-010/S-017/S-019 NDA 20-844 S-006/S-014/S-016." Approval of these submissions by FDA is not required before the labeling is used.

Promotional Material
In addition, submit three copies of the introductory promotional materials that you propose to use for these products. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

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

Dear Healthcare Professional Letter
As we agreed, you will send a "Dear Health Care Professional" letter informing health care professionals about the labeling changes pertaining to metabolic acidosis. When the letter is issued, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Jacqueline H. Ware, Pharm.D., Senior Regulatory Project Manager, at (301) 594-2850.

Sincerely,

{See appended electronic signature page}

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

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Russell Katz

12/16/03 04:18:53 PM