DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-505/S-016
NDA 20-844/S-013

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 application(s) dated May 30, 2002, received May 31, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Topamax (topiramate) Tablets and Topamax (topiramate capsules) Sprinkle Capsules.

We acknowledge receipt of your submissions dated August 15, 2002.

These "Changes Being Effected" supplemental new drug applications provide for a revision to the "Postmarketing and Other Experience" section of the Topamax package insert to delineate that some reports of hepatic failure have resulted in death.

We have completed our review of these supplemental new drug applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in your final printed labeling (FPL) submitted on August 15, 2002. Accordingly, these supplemental applications (NDA 20-505/S-016 and NDA 20-505/S-013) are approved effective on the date of this letter.

However, we note that your labeling submitted on August 15, 2002 also includes changes provided for in your pending (b)----------
(b)----------
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----------roval does not apply to the changes proposed in those pending supplemental applications. We are currently evaluating those data and will comment on those additions in a separate action letter.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), 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 Project Manager, at (301) 594-5533.

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

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

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