DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20-505/S-037 & NDA 20-844/S-031
NDA 20-505/S-032 & NDA 20-844/S-027
NDA 20-505/S-031 & NDA 20-844/S-026
NDA 20-505/S-014 & NDA 20-844/S-011

SUPPLEMENT APPROVAL

Ortho-McNeil-Janssen Pharmaceuticals, Inc.
c/o Johnson & Johnson Pharmaceutical Research & Development, L.L.C.
Attention: Stefan Ochalski, M.B.A.
1125 Trenton-Harbourton Road; P.O. Box 200
Titusville, N.J. 08560

Dear Mr. Ochalski:

Please refer to your supplemental new drug applications (sNDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Topamax® (topiramate) Tablets, 25, 50, 100 and 200 mg, and Topamax® (topiramate capsules) Sprinkle Capsules, 15 mg and 25 mg listed in the table below.

Application Numbers/Type	Letter Date	Receipt Date	Provides for	Additional Submissions
20-505/S-037 20-844/S-031 (Prior Approval/Efficacy)	April 24, 2008	April 25, 2008	Fulfills Pediatric Written Request; adds clinical trial data to the Pediatric Use subsection of the Use in Specific Populations section	July 2, 2009 July 27, 2009 December 18, 2009
20-505/S-032 20-844/S-027 (Prior Approval)	May 10, 2007	May 10, 2007	Adds Drug Interaction study information for diltiazem, venlafaxine, glyburide, lithium, risperidone.	
20-505/S-031 20-844/S-026 (Changes Being Effected)	April 26, 2007	April 26, 2007	To Warnings and Precautions: adds section for withdrawal of AEDs and, under the Laboratory Tests section, adds information about hypokalemia To Information for Patients: Adds information regarding vision disorders.	
20-505/S-014 20-844/S-011 (Changes Being Effected)	October 30, 2001	October 31, 2001	Adds drug interaction study information for metformin	November 13, 2001 January 28, 2001

Your submission of July 2, 2009 constituted a complete response to our January 23, 2009, action letter.

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

Within 14 days from the date of this letter, please amend all pending supplemental applications for this NDA, including pending "Changes Being Effected" (CBE) supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format that includes the changes approved in this supplemental application.

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable. PREA is not applicable for this application.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

REPORTING REQUIREMENTS

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 Susan Daugherty, Regulatory Project Manager, at (301) 796-0878.

Sincerely,

{See appended electronic signature page}

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

Enclosure: Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20505	SUPPL-14	ORTHO MCNEIL JANSSEN PHARMACEUTICALS INC	TOPAMAX (TOPIRAMATE) ORAL TABS 100MG/200
NDA-20505	SUPPL-31	ORTHO MCNEIL JANSSEN PHARMACEUTICALS INC	TOPAMAX (TOPIRAMATE) ORAL TABS 100MG/200
NDA-20505	SUPPL-32	ORTHO MCNEIL JANSSEN PHARMACEUTICALS INC	TOPAMAX (TOPIRAMATE) ORAL TABS 100MG/200
NDA-20505	SUPPL-37	ORTHO MCNEIL JANSSEN PHARMACEUTICALS INC	TOPAMAX (TOPIRAMATE) ORAL TABS 100MG/200
NDA-20844	SUPPL-11	ORTHO MCNEIL JANSSEN PHARMACEUTICALS INC	TOPAMAX(TOPIRAMATE)SPRINKLE CAPS 50/25/1
NDA-20844	SUPPL-26	ORTHO MCNEIL JANSSEN PHARMACEUTICALS INC	TOPAMAX(TOPIRAMATE)SPRINKLE CAPS 50/25/1
NDA-20844	SUPPL-27	ORTHO MCNEIL JANSSEN PHARMACEUTICALS INC	TOPAMAX(TOPIRAMATE)SPRINKLE CAPS 50/25/1
NDA-20844	SUPPL-31	ORTHO MCNEIL JANSSEN PHARMACEUTICALS INC	TOPAMAX(TOPIRAMATE)SPRINKLE CAPS 50/25/1

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

/s/

RUSSELL G KATZ
12/22/2009