DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-001 S-008
S-009

Johnson & Johnson Pharmaceutical Research & Development, L.L.C.
on behalf of: Ortho-McNeil Pharmaceutical, Inc.
Attention: Michael Kaufman
Director, Regulatory Affairs
1000 U.S. Highway 202, P.O. Box 300
Raritan, NJ 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 Axert (almotriptan malate) Tablets 6.25 and 12.5 mg.

Supplement Number:	Letter Date:	Receipt Date:
S-008	February 9, 2007	February 9, 2007
This supplemental new drug application was submitted in response to an Agency email dated December 20, 2006 and provides for revision of the WARNINGS, PRECAUTIONS; Drug Interactions section, and PRECAUTIONS; Information for Patients section of the package insert and to the Patient Package Insert to include information concerning serotonin syndrome with concomitant use of triptans and SSRIs/SNRIs.		
S-009	June 6, 2007	June 6, 2007
This supplemental new drug application was submitted in response to an Agency letter dated December 22, 2006 and provides for revision of the ADVERSE REACTIONS section of the package insert to include reports of seizure in close temporal association with triptan use in the "Postmarketing Experience" section of the label.		

We have completed our review of supplemental new drug applications S-008 and S-009 and they are approved, effective on the date of this letter, for use as recommended in the enclosed content of labeling [21 CFR 314.50(1)], which is identical to the content of labeling in Structured Product Labeling (SPL) format submitted to S-009 on June 6, 2007. To facilitate the transmission of labeling to the National Library of Medicine for public dissemination, please resubmit this content of labeling in SPL format as soon as possible, but no later than 14 days from the date of this letter. For administrative purposes, please designate this submission, "SPL for approved NDA 21-001." (or "SPL for approved supplements NDA 21-001/S-008/S-009.")

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 Ms. Lana Chen, Regulatory Project Manager, at (301) 796-1056.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Division Director
Division of Neurology 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

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