DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21-016/S-009/ S-016

SUPPLEMENT APPROVAL

Pfizer Inc.
Attention: Carol Haley
Director, Worldwide Regulatory Affairs
235 East 42nd Street
New York, NY 10017

Dear Ms. Haley:

Please refer to your Supplemental New Drug Applications (sNDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Relpax (eletriptan hydrobromide) Tablets.

SLR	Letter Date	Receipt Date
009	June 22, 2005	June 23, 2005
amended:	May 9, 2006	May 10, 2006
This "Changes Being Effected" supplemental new drug application was submitted in response to an Agency letter dated February 28, 2005 and provides revised language in the WARNINGS: Postmarketing Experience with Eletriptan subsection to include information involving serious cardiovascular events including acute myocardial infarction, disturbances in cardiac rhythm and death.		
016	April 30, 2007	May 1, 2007
This "Changes Being Effected" supplemental new drug application was submitted in response to an Agency Letter dated April 28, 2006 and provides information about Selective Serotonin Reuptake Inhibitors/Serotonin Norepinephrine Reuptake Inhibitors and Serotonin Syndrome. Language was also added to include seizure in the OTHER EVENTS OBSERVED DURING POST-MARKETING USE section as was requested by the Agency in a correspondence dated December 22, 2006.		

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

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR

314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling (text for the package insert, text for the patient package insert,) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, 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 MS Word format that includes the changes approved in this supplemental application.

If you have any questions, call 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:
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21016	SUPPL-16	PFIZER IRELAND PHARMACEUTICALS	RELPAX (ELETRIPTAN HYDROBROMIDE)20&40MG
NDA-21016	SUPPL-9	PFIZER IRELAND PHARMACEUTICALS	RELPAX (ELETRIPTAN HYDROBROMIDE)20&40MG

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/s/

RUSSELL G KATZ
07/21/2010