DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021016/S-021/S-023/S-024/S-027

SUPPLEMENT APPROVAL

Pfizer, Inc.
Attention: Denise S. Tindle, M.S.
Associate Director, Regulatory Strategy
445 Eastern Point Rd.
Groton, CT 06340

Dear Ms. Tindle:

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

Supplement Number	Submitted on:	Received on:	Submission Classification	Proposed Change
S-021	May 18, 2011	May 18, 2011	Changes Being Effected	Update the Precautions Section of the USPI
S-023	February 2, 2012	February 2, 2012	Changes Being Effected-30	The addition of: Immune System Disorders: Allergic reactions, some of which may be serious, including angioedema.
S-024	June 29, 2012	June 29, 2012	Prior Approval Supplement	PLR Conversion
S-027	August 19, 2013	August 19, 2013	Changes Being Effected	Revise the Warnings section text with regards to Increase in Blood Pressure

We acknowledge receipt of your amendments dated:

Supplement Number	Submitted on:	Received on:
S-021	February 19, 2012	February 19, 2012
S-023	November 20, 2012	November 20, 2012
S-024	February 27, 2012	February 27, 2012
S-024	September 27, 2013	September 27, 2013

APPROVAL & LABELING

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

We note that your September 27, 2013, submission includes final printed labeling (FPL) for your package insert, and patient package insert. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert, text for the patient package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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 that includes labeling changes for this NDA, including 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, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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

Sincerely,

{See appended electronic signature page}

Eric Bastings, M.D.
Acting Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

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

/s/

ERIC P BASTINGS
10/03/2013