DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20235/S-064
NDA 20882/S-047
NDA 21129/S-046

SUPPLEMENT APPROVAL

Pfizer, Inc.
445 Eastern Point Road
Groton, CT 06340

Attention: Larry Cheng, MS
Manager, Essential Health Global Regulatory Affairs Brand

Dear Mr. Cheng:

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received April 19, 2017, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following: Neurontin (gabapentin) capsules (N020235), tablets (N020882), and oral solution (N021129).

Application	Product	Submitted on:	Received on:
NDA 20235/S-064	Neurontin Capsules	April 19, 2017	April 19, 2017
NDA 20882/S-047	Neurontin Tablets	April 19, 2017	April 19, 2017
NDA 21129/S-046	Neurontin Oral Solution	April 19, 2017	April 19, 2017

These "Prior Approval" Supplemental New Drug Applications provide for the following changes: labeling consistent with the Pregnancy and Lactation Labeling Rule (PLLR), and minor editorial changes to the prescribing information.

APPROVAL & LABELING

We have completed our review of these supplemental applications, as amended. The applications 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 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, Medication Guide), 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 include 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).

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.

Because none of these criteria apply to your applications, you are exempt from this requirement.

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, contact/call Cathy Michaloski, Sr. Regulatory Project Manager, at Cathleen.michaloski@fda.hhs.gov or (301) 796-1123.

Sincerely,

{See appended electronic signature page}

Alice Hughes, M.D.
Deputy Director for Safety
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE:
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/

ALICE HUGHES
10/18/2017