



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Silver Spring MD 20993

NDA 020235/S-060  
NDA 020882/S-043  
NDA 021129/S-042

**SUPPLEMENT APPROVAL**

Parke-Davis  
Subsidiary of Pfizer, Inc.  
235 East 42<sup>nd</sup> Street  
New York, NY 10017

Attention: Denise S. Tindle, M.S.  
Director, Worldwide Safety & Regulatory

Dear Ms. Tindle:

Please refer to your Supplemental New Drug Applications (sNDA) dated and received September 18, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Neurontin (gabapentin) capsules (N020235), tablets (N020882), and syrup (N021129).

We acknowledge receipt of your amendments dated July 2, 2015, and August 11, 2015.

These Prior Approval supplemental new drug applications provide for changes to the prescribing information in several sections of the labeling, including the addition of several adverse reactions to Adverse Reactions—Postmarketing Experience (6.2), updates to Drug Interactions related to concomitant use with opioids (7), the addition of information about coma events to Overdosage (10), the addition of anaphylaxis and angioedema to Warnings and Precautions (5.2), and Patient Counseling Information (17), as well as related changes to the Medication Guide.

**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, 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 these NDAs, 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 these supplemental applications, 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 Cathy Michaloski, Sr. Regulatory Project Manager, at (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

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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ALICE HUGHES  
09/14/2015