



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020235/S-061
NDA 020882/S-044
NDA 021129/S-043

SUPPLEMENT APPROVAL

Parke-Davis
Subsidiary of Pfizer, Inc.
235 East 42nd 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 October 23, 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 amendment dated November 6, 2014, and April 16, 2015.

These Prior Approval supplemental new drug applications provide changes to the prescribing information, specifically Section 12.1 (Clinical Pharmacology) Mechanism of Action.

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}

Eric P. Bastings, M.D.
Deputy Director
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/

ERIC P BASTINGS
04/21/2015