



NDA 22006/S-17

**SUPPLEMENT APPROVAL**

Lundbeck LLC  
Attention: Gregg Pratt, PhD  
Acting Vice President, Regulatory Affairs  
Four Parkway North  
Deerfield, IL 60015

Dear Dr. Pratt:

Please refer to your Supplemental New Drug Application (sNDA) dated October 20, 2015, received October 20, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Sabril (vigabatrin) powder for oral solution 500 mg.

We also refer to our email dated September 22, 2015, in which we requested revisions to the carton and container labeling to mitigate the risk of wrong technique errors related to preparation, handling and storage of Sabril (vigabatrin) powder for oral solution.

This supplemental new drug application provides for revisions to the carton and container labeling for Sabril (vigabatrin) powder for oral solution 500 mg, consistent with our September 22, 2015, email recommending that the "Directions for Use" section on the carton labeling and single dose foil package be revised.

**APPROVAL & LABELING**

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

**CARTON AND IMMEDIATE CONTAINER LABELS**

We acknowledge your October 20, 2015, submission containing final printed carton and container labels.

**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 Heather Bullock, Regulatory Project Manager, via email at [heather.bullock@fda.hhs.gov](mailto:heather.bullock@fda.hhs.gov) or via telephone at (301) 796-1126.

Sincerely,

*{See appended electronic signature page}*

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

ENCLOSURE(S):  
Carton and Container 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  
11/03/2015