



NDA 020427/S-023

## SUPPLEMENT APPROVAL

Lundbeck Pharmaceuticals LLC  
Attention: Nancy Aiello  
Director, US Regulatory Affairs  
Six Parkway North, Suite 400  
Deerfield, IL 60015

Dear Ms. Aiello:

Please refer to your Supplemental New Drug Application (sNDA) dated and received April 21, 2020, and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Sabril (vigabatrin) Tablets, 500 mg.

This “Changes Being Effected” supplemental new drug application provides for the addition of a Sabril tablet carton label as a new packaging component to meet serialization requirements.

### **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.

### **CARTON AND CONTAINER LABELS**

Submit final printed carton label that is identical to enclosed carton label, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission “**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 020427/S-023.**” Approval of this submission by FDA is not required before the labeling is used.

### **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 Avani Patel, Regulatory Business Process Manager, at (240) 402 - 1845.

Sincerely,

*{See appended electronic signature page}*

David Lewis, Ph.D.  
Branch Chief  
Division of Post-Marketing Activities I  
Office of Lifecycle Drug Products  
Office of Pharmaceutical Quality  
Center for Drug Evaluation and Research

Enclosures:

Carton Labeling



David  
Lewis

Digitally signed by David Lewis  
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