



NDA 21168/S-030

SUPPLEMENT APPROVAL

AbbVie Inc.
Attention: Jennifer Field, MS, Associate Director, Regulatory Affairs
1 N. Waukegan Road
Sept. PA77/Bldg. AP30-1
North Chicago, IL 60064

Dear Ms. Field:

Please refer to your Supplemental New Drug Application (sNDA) dated September 22, 2014, received September 22, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Depakote ER (divalproex sodium) Extended-Release Tablets.

This “Prior Approval” supplemental new drug application provides for revising the carton and container labels with a prominent ‘Once-Daily Dosing’ statement.

We have completed our review of this supplemental application. This supplement is approved.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the enclosed carton and immediate container labels submitted on September 22, 2014, 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 – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission “**Final Printed Carton and Container Labels for approved NDA 21168/S-030.**” Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 Teshara G. Bouie, Regulatory Business Process Manager, at (301) 796-1649.

Sincerely,

Hasmukh Patel, Ph.D.
Division Director (Acting)
Division of Post Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

**Hasmukh
B. Patel -S**

Digitally signed by Hasmukh B. Patel -S
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ENCLOSURES:
Carton and Container Labeling