DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 018081/S-062
NDA 018082/S-045
NDA 018723/S-054
NDA 019680/S-041
NDA 020593/S-032
NDA 021168/S-031

SUPPLEMENT APPROVAL

AbbVie, Inc.
Attention: Patti Neall
Associate Director, Regulatory Affairs
1 North Waukegan Road
Dept. PA77/Bldg. AP30
North Chicago, IL 60064

Dear Ms. Neall:

Please refer to your Supplemental New Drug Applications (sNDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

Application	Drug Product	Submitted on:	Received on:
NDA 018081/S-062	Depakene (valproic acid) Capsules	9/30/2014	9/30/2014
NDA 018082/S-045	Depakene (valproic acid) Oral Solution		
NDA 018723/S-054	Depakote (divalproex sodium) Delayed Release Tablets		
NDA 019680/S-041	Depakote Sprinkle Capsules (divalproex sodium delayed release capsules)		
NDA 020593/S-032	Depacon (valproate sodium) Injection		
NDA 021168/S-031	Depakote ER (divalproex sodium) Extended Release Tablets		

We acknowledge receipt of your amendments dated December 15, 2014, and January 30, 2015.

These Prior Approval supplemental new drug applications provide for the following:

Section 6: Adverse Reactions—Post-Marketing Experience: The addition of hair texture changes and hair color changes to the dermatologic subsection; the addition of hyperandrogenism, hirsutism, and elevated testosterone level to the endocrine subsection

Section 10: Overdosage: The addition of hypernatremia to the description of the possible consequences of valproate overdosage

APPROVAL & LABELING

We have completed our review of these supplemental applications, as amended. They 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 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, using the FDA automated drug registration 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 (text for package insert and Medication Guide), 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/Drugs/GuidanceComplianceRegulatoryInformation/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(1)(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 MS Word version. The marked-up copy should provide appropriate annotations, including supplemental 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, contact Cathy Michaloski, Sr. Regulatory Project Manager, at (301) 796-1123, or by email at Cathleen.michaloski@fda.hhs.gov

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 and Evaluation Research

ENCLOSURE(S):
Content of Labeling