DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 18081/S-068
NDA 18082/S-051
NDA 18723/S-060
NDA 19680/S-047
NDA 20593/S-038
NDA 21168/S-038

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 Application (sNDA) dated and received September 12, 2017, 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 18081/S-068	Depakene (valproic acid) Capsules	9/12/2017	9/12/2017
NDA 18082/S-051	Depakene (valproic acid) Oral Solution		
NDA 18723/S-060	Depakote (divalproex sodium) Delayed Release Tablets		
NDA 19680/S-047	Depakote Sprinkle Capsules		
NDA 20593/S-038	Depacon (valproate sodium) Injection		
NDA 21168/S-038	Depakote ER (divalproex sodium) Extended Release Tablets		

We also refer to our approval letter dated March 6, 2018 which contained the following error: omission of NDA 19680/S-047 Depakote Sprinkle Capsules Prescribing Information.

This replacement approval letter incorporates the correction of the error. The effective approval date will remain March 6, 2018, the date of the original approval letter.

These Changes Being Effected (CBE) supplemental new drug applications provide for the addition of "parkinsonism" to Subsection 6.4 of the Prescribing Information (Adverse Reactions; Post-Marketing Experience; Neurologic).

APPROVAL & LABELING

We have completed our review of these supplemental applications. The supplements 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 (text for the 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/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 submissions, 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).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived,

deferred, or inapplicable.

Because none of these criteria apply to your applications, you are exempt from this requirement.

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 Cathleen Michaloski, BSN, MPH, Sr. Regulatory Project Manager, by email Cathleen.michaloski@fda.hhs.gov or phone at (301) 796-1123.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURES:
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/

ALICE HUGHES
03/06/2018