DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 18081/S-066
NDA 18082/S-049
NDA 18723/S-058
NDA 19680/S-045
NDA 20593/S-036
NDA 21168/S-036

SUPPLEMENT APPROVAL

AbbVie, Inc.
1 North Waukegan Road
Dept. PA77/Bldg. AP30
North Chicago, IL 60064

Attention: Patti Neall
Associate Director, Regulatory Affairs

Dear Ms. Neall:

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received September 6, 2016, and your amendments, 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-066	Depakene (valproic acid) Capsules	September 6, 2016	September 6, 2016
NDA 018082/S-049	Depakene (valproic acid) Oral solution		
NDA 018723/S-058	Depakote (divalproex sodium delayed release tablets)		
NDA 019680/S-045	Depakote Sprinkle Capsules (divalproex sodium delayed release capsules)		
NDA 020593/S-036	Depacon (valproate sodium) Injection		
NDA 021168/S-036	Depakote ER (divalproex sodium) Extended Release Tablets		

These Prior Approval Supplemental New Drug Applications provide for the addition of information describing reports of encephalopathy in the absence of elevated ammonia levels to Subsection 6.4, and of information describing an interaction with estrogen-containing hormonal contraceptives to Subsection 7.1 of the Prescribing Information.

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 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), 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 this NDA, 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 this supplemental application, 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 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 Brenda Reggettz, Pharm.D., Regulatory Project Manager, by email at Brenda.Reggettz@fda.hhs.gov or by phone at (240) 402-6220.

Sincerely,

{See appended electronic signature page}

Eric P. Bastings, M.D.
Deputy Director
Office of Drug Evaluation I
Division of Neurology Products
Center for Drug Evaluation and Research

ENCLOSURE:
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/

ERIC P BASTINGS
03/06/2017