



NDA 018081/S-058  
NDA 018082/S-041  
NDA 018723/S-050  
NDA 019680/S-037  
NDA 020593/S-028  
NDA 021168/S-026

**SUPPLEMENT APPROVAL**

AbbVie, Inc.  
Attention: Jennifer Field, M.S.  
Associate Director, Regulatory Affairs – US & Canada  
1 North Waukegan Road  
Dept. PA77/Bldg. AP30  
North Chicago, IL 60064

Dear Ms. Field:

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-058	Depakene (valproic acid) Capsules	4/22/2013	4/23/2013
NDA 018082/S-041	Depakene (valproic acid) Oral Solution		
NDA 018723/S-050	Depakote (divalproex sodium) Delayed Release Tablets		
NDA 019680/S-037	Depakote Sprinkle Capsules (divalproex sodium coated particles in capsules)		
NDA 020593/S-028	Depacon (valproate sodium) Injection		
NDA 021168/S-026	Depakote ER (divalproex sodium) Extended Release Tablets		

We acknowledge receipt of your amendments dated September 11, 2013, August 11, 2014, and November 17, 2014.

These Prior Approval supplemental new drug applications provide for the addition of cerebral pseudoatrophy to Section 6.4 of the Prescribing Information.

## **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 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(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 this NDA, 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 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 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).

NDA 018081/S-058  
NDA 018082/S-041  
NDA 018723/S-050  
NDA 019680/S-037  
NDA 020593/S-028  
NDA 021168/S-026  
Page 3

If you have any questions, call Cathy Michaloski, Sr. Regulatory Project Manager, at (301) 796-1123, or by email at [Cathleen.michaloski@fda.hhs.gov](mailto: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

-----  
**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  
11/20/2014