



NDA 18081/S-064
NDA 18082/S-047
NDA 18723/S-056
NDA 19680/S-043
NDA 20593/S-034
NDA 21168/S-033

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:

We have received your Supplemental New Drug Applications (sNDA) submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA or the Act) for the following:

Application	Drug Product	Submitted on:	Received on:
NDA 018081/S-064	Depakene (valproic acid) Capsules	8/21/2015	8/21/2015
NDA 018082/S-047	Depakene (valproic acid) Oral Solution		
NDA 018723/S-056	Depakote (divalproex sodium) Delayed Release Tablets		
NDA 019680/S-043	Depakote Sprinkle Capsules		
NDA 020593/S-034	Depacon (valproate sodium) Injection		
NDA 021168/S-033	Depakote ER (divalproex sodium) Extended Release Tablets		

These supplemental applications provide for the following changes: addition of new safety language to the following sections of the prescribing information:

6.4 Adverse Reactions; Post-Marketing Experience

Dermatologic: addition of nail and nail bed disorders;

Metabolism and nutrition: addition of weight gain

7 DRUG INTERACTIONS

- 7.1 Effects of Co-Administered Drugs on Valproate Clearance: addition of cholestyramine (in the prescribing information for Depakene [valproic acid] capsules and oral solution only)
- 7.2 Effects of Valproate on Other Drugs: addition of rufinamide

APPROVAL & LABELING

We have completed our review of these supplemental applications. The applications 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, 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 Q’s and A’s” 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).

NDA 18081/S-064
NDA 18082/S-047
NDA 18723/S-056
NDA 19680/S-043
NDA 20593/S-034
NDA 21168/S-033

Page 3

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 Cathy Michaloski, Sr. Regulatory Project Manager, at (301) 796-1123.

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 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/

ALICE HUGHES
02/18/2016