DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 18081/S-063
NDA 18082/S-046
NDA 18723/S-055
NDA 19680/S-042
NDA 20593/S-033
NDA 21168/S-032

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-063	Depakene (valproic acid) Capsules	4/23/15	4/23/15
NDA 018082/S-046	Depakene (valproic acid) Oral Solution		
NDA 018723/S-055	Depakote (divalproex sodium) Delayed Release Tablets		
NDA 019680/S-042	Depakote Sprinkle Capsules (divalproex sodium delayed release capsules)		
NDA 020593/S-033	Depacon (valproate sodium) Injection		
NDA 021168/S-032	Depakote ER (divalproex sodium) Extended Release Tablets		

These Prior Approval supplemental new drug applications provide for the addition of a new Reproductive subsection to the Adverse Reactions—Post-Marketing Experience section (6.4). The new subsection includes the following terms: aspermia, azoospermia, decreased sperm count, decreased spermatozoa motility, male infertility, and abnormal spermatozoa morphology.

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

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
09/23/2015