NDA 018081/S-071
NDA 018082/S-054
NDA 018723/S-063
NDA 019680/S-050
NDA 020593/S-041
NDA 021168/S-041

SUPPLEMENT APPROVAL

AbbVie Inc.
Attention: David Desris, R.Ph., Pharm.D.
Director, Regulatory Affairs
1 North Waukegan Road
Dept. PA72/Bldg. AP30-1
North Chicago, IL 60064

Dear Dr. Desris:

Please refer to your supplemental new drug applications (sNDAs) dated November 20, 2019, received November 20, 2019, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Depakene (valproic acid) capsules, Depakene (valproic acid) oral solution, Depakote (divalproex sodium) delayed-release tablets, Depakote sprinkle capsules (divalproex sodium delayed release capsules), Depacon (valproate sodium) injection, and Depakote ER (divalproex sodium) extended-release tablets.

These Prior Approval supplemental new drug applications provide for revisions to Section 8.1 (Use in Specific Populations; Pregnancy) of the Prescribing Information and to the Medication Guide to reflect new data pertaining to an increased risk of attention deficit/hyperactivity disorder (ADHD) in children who were exposed to valproate *in utero*.

APPROVAL & LABELING

We have completed our review of these applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

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 FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information 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 *SPL Standard for Content of Labeling Technical Qs and As*.[2]

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 Microsoft Word format, that includes the changes approved in these supplemental applications, as well as annual reportable changes. To facilitate review of your submission(s), 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).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.gov

If you have any questions, call Stephanie N. Parncutt, M.H.A., Senior Regulatory Health Project Manager, at (301) 796-4098 or email at Stephanie.Parncutt@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Alice Hughes, M.D.
Deputy Director for Safety
Division of Neurology 2
Office of Neuroscience
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Medication Guide

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

ALICE HUGHES
05/19/2020 01:31:52 PM