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:

<table>
<thead>
<tr>
<th>Application</th>
<th>Drug Product</th>
<th>Submitted on</th>
<th>Received on</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDA 018082/S-041</td>
<td>Depakene (valproic acid) Oral Solution</td>
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<tr>
<td>NDA 018723/S-050</td>
<td>Depakote (divalproex sodium) Delayed Release Tablets</td>
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<tr>
<td>NDA 019680/S-037</td>
<td>Depakote Sprinkle Capsules (divalproex sodium coated particles in capsules)</td>
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<tr>
<td>NDA 020593/S-028</td>
<td>Depacon (valproate sodium) Injection</td>
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<tr>
<td>NDA 021168/S-026</td>
<td>Depakote ER (divalproex sodium) Extended Release Tablets</td>
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</tbody>
</table>

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).
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

Sincerely,

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