



NDA 018081/S-054
NDA 018082/S-038
NDA 018723/S-047
NDA 019680/S-034
NDA 020593/S-025
NDA 021168/S-023

SUPPLEMENT APPROVALS

AbbVie Inc.
Attention: Gary Magistrelli, PhD.
Associate Director, Regulatory Affairs
1 N. Waukegan Road
Dept. PA77/Bldg. AP30
North Chicago, IL 60064

Dear Dr. Magistrelli:

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-054	Depakene (valproic acid) Capsules	07/10/2012	07/10/2012
NDA 018082/S-038	Depakene (valproic acid) Oral Solution		
NDA 018723/S-047	Depakote (divalproex sodium) Delayed Release Tablets		
NDA 019680/S-034	Depakote Sprinkle Capsules (divalproex sodium coated particles in capsules)		
NDA 020593/S-025	Depacon (valproate sodium) Injection		
NDA 021168/S-023	Depakote ER (divalproex sodium) Extended Release Tablets		

These “Prior Approval Supplements” supplements provide for:

Correcting errors in the approved labeling described in the October 7, 2011 action letter. The labels submitted were agreed upon via electronic communication on May 23, 2012.

We also refer to our approval letter dated February 27, 2013, which contained the following error: Product Name for NDA 19680 Depakote Sprinkle Capusles (divalproex sodium coated particles in capsules) was incorrect in the highlights section of the attached package insert.

NDA 018081/S-054
NDA 018082/S-038
NDA 018723/S-047
NDA 019680/S-034
NDA 020593/S-025
NDA 021168/S-023
Page 2

This replacement approval letter incorporates the correction of the error. The effective approval date will remain February 27, 2013, the date of the original approval letter.

We have completed our review of these supplemental applications. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text. The Agency requests that you implement this language during the next printing cycle of these products' 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 <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the package insert, patient 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/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes 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(l)(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 Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory

NDA 018081/S-054
NDA 018082/S-038
NDA 018723/S-047
NDA 019680/S-034
NDA 020593/S-025
NDA 021168/S-023
Page 3

comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at <http://www.fda.gov/opacom/morechoices/fdaforms/cder.html>; instructions are provided on page 2 of the form. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

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 Stacy Metz, PharmD, Regulatory Project Manager, at (301) 796-2139.

Sincerely,

{See appended electronic signature page}

Russell G. Katz, MD
Director
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/

RUSSELL G KATZ
02/27/2013