



NDA 016608/S-099  
NDA 018281/S-047  
NDA 018927/S-040  
NDA 020234/S-030

## SUPPLEMENT APPROVAL

Novartis Pharmaceuticals Corporation  
Attention: Rebecca Kaplan, MS, RAC  
Global Program Regulatory Manager, Drug Regulatory Affairs  
One Health Plaza  
East Hanover, NJ 07936-1080

Dear Ms. Kaplan:

Please refer to your Supplemental New Drug Applications dated September 2, 2008, received September 2, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Tegretol (carbamazepine) Tablets, Tegretol (carbamazepine) Chewable Tablets, Tegretol (carbamazepine) Oral Suspension, and Tegretol-XR (carbamazepine extended-release) Tablets.

We acknowledge receipt of your amendments dated March 28, 2011; September 25, 2013; February 6, 2014 and June 23, 2014.

These "Prior Approval" supplemental new drug applications propose changes to the **Drug Interactions, Pharmacokinetics, and Adverse Reactions** sections of the Package Insert (PI).

### **APPROVAL & LABELING**

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.

### **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 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.

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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 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/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>.

Information and Instructions for completing the form can be found at

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>. 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).

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If you have any questions, call Stephanie N. Parncutt, MHA, Regulatory Project Manager, at (301) 796-4098.

Sincerely,

*{See appended electronic signature page}*

Eric Bastings, M.D.

Deputy Director

Division of Neurology Products

Office of Drug Evaluation I

Center for Drug Evaluation and Research

ENCLOSURE(S):

Content of Labeling

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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ERIC P BASTINGS  
09/16/2014