DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-014/S-021
NDA 21-285/S-014

Novartis Pharmaceuticals Corporation
Attention: Peter McCardle, D.V.M.
Director, Drug Regulatory Affairs
One Health Plaza
East Hanover, NJ 07936-1080

Dear Dr. McCardle:

Please refer to your supplemental new drug applications (NDAs) dated and received on April 27, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Trileptal® (oxcarbazapine) Tablets and Solution.

These "Changes Being Effected" supplemental NDAs provide for revisions to the **WARNINGS, PRECAUTIONS, INFORMATION FOR PATIENTS,** and **ADVERSE REACTIONS** sections of the package insert to add information regarding anaphylactic reactions and angioedema.

We completed our review of these supplemental NDAs and they are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on April 27, 2007.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Susan Daugherty, Regulatory Project Manager, at (301) 796-0878.

Sincerely,

{See appended electronic signature page}

Russell Katz, MD
Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Russell Katz

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