DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 16-608/S-096; NDA 18-281/S-044
NDA 18-927/S-035; NDA 20-234/S-025

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 dated November 25, 2003, received November 26, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tegretol (carbamazepine) Tablets, Chewable Tablets, Suspension, and Extended-Release Tablets.

We acknowledge receipt of your submissions dated July 27, 2007.

These "Changes Being Effected" supplemental new drug applications provide for revisions to the CONTRAINDICATIONS, WARNINGS, and PRECAUTIONS sections of the package insert.

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

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions "**FPL for approved supplement NDA 16-608/S-096, NDA 18-281/S-044; NDA18-927/S-035; NDA 20-234/S-025**." Approval of these submissions by FDA is not required before the labeling is used.

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, M.D.
Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure: 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 Katz

8/16/2007 05:01:49 PM