DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-014/SLR-012
NDA 21-285/SLR-007

Novartis Pharmaceuticals
Attention: Peter McArdle, DVM
One Health Plaza
Hanover, NJ 07936-1080

Dear Dr. McArdle:

Please refer to your supplemental new drug applications dated September 30, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Triletpal® (oxcarbazepine) Tablets and Oral Solution.

We acknowledge receipt of your submission dated February 7, 2005.

These supplemental new drug applications provide for additional language regarding reports of serious dermatological reactions and reports of multi-organ hypersensitivity reactions occurring in association with Trileptal use.

We completed our review of these applications, as amended. These applications 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 attached labeling text.

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 21-014/SLR-012 and NDA 21-285/S-007**. Approval of these submissions by FDA is not required before the labeling is used.

We note that you will be issuing 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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Melina Griffis, R.Ph., Sr. Regulatory Project Manager, at (301) 594-5526.

Sincerely,

{See appended electronic signature page}

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

Enclosure

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
3/25/05 03:20:28 PM