DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-014/S-007
NDA 21-285/S-004

Novartis Pharmaceutical Corporation
Attention: Ramona Cheng, Associate Director
TRD/Global Regulatory CMC
One Health Plaza
East Hanover, NJ 07936-1080

Dear Ms. Cheng:

Please refer to your supplemental new drug applications dated November 25, 2002, received November 29, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Trileptal® (oxcarbazepine) Tablets and Trileptal® (oxcarbazepine) Oral Suspension.

The supplemental applications provide for a new synthetic route for oxcarbazepine, using new starting material and different chemicals to eliminate the need for (b)(4)----------

We have completed the review of these supplemental applications and they are approved. Please provide your commitment to submit information for the following comments:

1. The use of (b)(4)----------without previous analysis should be adequately controlled to ensure that there is no adverse effect on the identity, strength, quality and purity, or potency of the drug substance. The applicant should provide data to demonstrate that use of (b)(4)----------does not adversely impact on impurity levels.

2. The combination of several batches for work-up should be adequately controlled to ensure that there is no adverse effect on the identity, strength, quality and purity, or potency of the drug substance. The applicant should provide data to demonstrate that this practice does not adversely impact on drug substance quality.

3. If a batch of an intermediate or the drug substance fails to meet specifications, reworking operations for the material should be developed post-approval, and the application should be updated through submission of a prior approval supplement.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact Jacqueline H. Ware, Project Manager, at (301) 594-2850.

Sincerely,

{See appended electronic signature page}

Maria E. Guzewska, Ph.D.
Chemistry Team Leader, Neurology Drugs for the
Division of Neuropharmacological Drug Products,
HFD-120
DNDC I, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Maryla Guzewska

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