DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

Food and Drug Administration
Rockville MD 20857

NDA 21-014/SLR-006
NDA 21-285/SLR-002

Novartis Pharmaceuticals Corporation
Attention: Mara Stiles
Associate Director, Drug Regulatory Affairs
59 Route 10
East Hanover, New Jersey 07936-1080

Dear Ms. Stiles:

Please refer to your supplemental new drug applications dated January 3, 2002, received January 23, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Trileptal (oxcarbazepine) Tablets & Oral Suspension

These "Changes Being Effected in 30 days" supplemental new drug applications provide for:

1. In the WARNINGS section of labeling, under the Hyponatremia section, in the last sentence of the second paragraph, adding “seizure” to the list of potential symptoms/signs of hyponatremia that should lead to measurement of serum sodium. That sentence reads as follows: “Measurement of serum sodium levels should be considered for patients during maintenance treatment with Trileptal, particularly if the patient is receiving other medications known to decrease serum sodium levels (for example, drugs associated with inappropriate ADH secretion) or if symptoms possibly indicating hyponatremia develop (e.g. nausea, malaise, headache, lethargy, confusion, obtundation, or increase in seizure frequency or severity).

2. In the ADVERSE REACTIONS section of labeling, under the “other events observed in association with the administration of Trileptal”, adding urticaria to the Skin and Appendages section.

We have completed the review of these supplemental applications and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the submitted final printed labeling. Accordingly, these supplemental applications are approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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, call Melina Fanari, R.Ph., Senior Regulatory Management Officer, 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

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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