NDA 16-608/S-090
NDA 18-281/S-039
NDA 18-927/S-031
NDA 20-234/S-017

7 MAR 2001

Novartis Pharmaceuticals Corporation
Attention: Mara Stiles
59 Route 10
East Hanover, New Jersey 07936-1080

Dear Ms. Stiles:

Please refer to your supplemental new drug applications dated April 21, 2000, received April 27, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tegretol (carbamezepine) Drug Products.

These "Changes Being Effected" supplemental new drug applications provide for the replacement of the sentence “Damaged tablets should not be consumed” with the following sentence in the Dosage and Administration section of labeling:

“Damaged tablets or tablets without a release portal should not be consumed.”

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., Regulatory Management Officer, at (301) 594-5526.

Sincerely,

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