DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19429/SLR-006

Novartis Pharmaceuticals Corporation
Attention: Martina Struck, Ph.D.
Regulatory Affairs Manager
Therapeutic Area: Nervous System
Drug Regulatory Affairs-419/1164
One Health Plaza
East Hanover, NJ 07936

Dear Dr.Struck:

Please refer to your supplemental new drug application dated February 1, 1985, received February 4, 1985, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Fiorinal ® with Codeine (butalbital, aspirin, caffeine, and codeine phosphate) Capsules.

We acknowledge receipt of your submissions dated February 14, 1995, January 29 and April 30, 1996.

This supplement provides for changes to the **CLINICAL PHARMACOLOGY** section.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted April 30, 1996). Accordingly, the supplemental application is 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 Nancy Halonen, Regulatory Health Project Manager, at (301) 827-2019.

Sincerely,

{See appended electronic signature page}

Lee S. Simon, M.D.
Director
Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products
Office of Drug Evaluation V
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/

Lee Simon

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