DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 9-000/S-022/S-023

Novartis Pharmaceuticals Corp.
Drug Regulatory Affairs
Attention: Martina Struck, PhD
419/1164
59 Route 10
East Hanover, NJ 07936

Dear Ms. Struck:

Please refer to your supplemental new drug applications dated October 8, 1999, received October 15, 1999 and December 22, 1999, received December 27, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cafergot (ergotamine tartrate and caffeine) suppositories.

We acknowledge receipt of your submissions dated July 7, 2000, February 25, 2002 and April 16, 2002. Your submission of April 16, 2002 constituted a complete response to our June 29, 2001 approvable letter.

These supplemental application provide for proposed labeling describing the risk of drug-drug interactions with CYP3A4 inhibitors, as well as the risk of cardiac valvular fibrosis.

We have completed the review of these supplemental applications 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 agreed upon labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling.

Please submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed to each application. Please mount individually ten of the copies on heavy-weight paper or similar material. Please also submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – NDAs* (January 1999). For administrative purposes, this/these submission(s) should be designated "FPL for approved supplement NDA 9-000/S-022/S-023 ." Approval of this/these submission(s) by FDA is not required before the labeling is used.

We acknowledge your commitment to issue a "Dear Health Care Practitioner" letter to physicians and others responsible for patient care. At the time that this letter issues to health care practitioners, we request that you submit a copy of the letter and label to this NDA, the electronic document room (EDR), 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 Ms. Lana Chen, R.Ph., Regulatory Project Manager, at (301) 594-5529.

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
6/4/02 09:16:17 AM