NDA 20-261/S-024

Novartis Pharmaceuticals Corporation
Attention: Adrian L. Birch
Executive Director, Drug Regulatory Affairs
59 Route 10
East Hanover, New Jersey 07936-1080

Dear Mr. Birch:

Please refer to your supplemental new drug application dated December 22, 1999, received December 23, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lescol (fluvastatin sodium) capsules.

We acknowledge receipt of your submission dated October 20, 2000.

This supplemental new drug application provides for changes to the Lescol (fluvastatin sodium) package insert as follows:

1) the addition to the **Distribution** and **Metabolism** subsections of the **CLINICAL PHARMACOLOGY** section of statements regarding the distribution and metabolism of fluvastatin and

2) the addition to the **Drug Interactions** subsection of the **PRECAUTIONS** section of summaries of fluvastatin drug interaction studies involving several drugs commonly coadministered with Lescol.

We have completed the review of this application 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 agreed-upon labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted October 20, 2000.

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. Please individually mount ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999). For administrative purposes, this submission should be designated "FPL for approved NDA 20-261/S-024." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" 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 William C. Koch, R.Ph., Regulatory Project Manager, at (301) 827-6412.

Sincerely,

David G. Orloff, M.D.
Director
Division of Metabolic
and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research