DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-261/S-032
NDA 21-192/S-004

Novartis Pharmaceuticals Corporation
Attention: Lisa N. Pitt, Pharm.D.
Assistant Director, Drug Regulatory Affairs
One Health Plaza
East Hanover, NJ 07936-1080

Dear Dr. Pitt:

Please refer to your supplemental new drug applications dated January 21, 2002, received January 22, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lescol (fluvastatin sodium) Capsules (NDA 20-261), Lescol XL (fluvastatin sodium) Extended-Release Tablets (NDA 21-192).

We acknowledge receipt of your submissions dated February 11, July 22 and 30 and August 23, 2002. Your submission of July 30, 2002, constituted a complete response to our July 18, 2002, action letter.

These supplemental new drug applications provide for:

> Revision of the **Elimination** subsection of the **CLINICAL PHARMACOLOGY** section of the approved package insert, incorporating results of a study evaluating steady state pharmacokinetics of fluvastatin sodium following administration of Lescol XL 80 mg Tablets.

We have completed the review of these supplemental applications, as amended, 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 final printed labeling labeling submitted on August 23, 2002. Accordingly, these supplemental applications are approved effective on the date of this letter.

In addition, please submit three copies of the introductory promotional materials that you propose to use for these products. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package inserts directly to:

> Division of Drug Marketing, Advertising, and Communications, HFD-42
> Food and Drug Administration
> 5600 Fishers Lane
> Rockville, Maryland 20857

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 William C. Koch, R.Ph., Regulatory Project Manager, at (301) 827-6412.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic
and Endocrine Drug Products, HFD-510
Office of Drug Evaluation II
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/

David Orloff

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