DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-261/S-033
NDA 21-192/S-005

Novartis Pharmaceuticals Corporation
Attention: Lisa N. Pitt, PharmD
Associate Director, Drug Regulatory Affairs
59 Route 10
East Hanover, New Jersey
07936-1080

Dear Dr. Pitt:

Please refer to your supplemental new drug applications dated July 31, 2002, received August 1, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lescol (fluvastatin sodium) Capsules (NDA 20-261) and Lescol XL (fluvastatin sodium) Extended-Release Tablets (NDA 21-192).

We acknowledge receipt of your submissions dated August 9 and November 4 (NDA 21-192), 2002, and January 16, April 2 and 29, and May 9 and 20, 2003.

These supplemental new drug applications provide for a new indication, based on the results of the Lescol Intervention Prevention Study (LIPS), for the use of fluvastatin in patients with coronary heart disease to reduce the risk of undergoing coronary revascularization procedures. In addition, these supplemental applications provide for changes to the CLINICAL PHARMACOLOGY, INDICATIONS AND USAGE, and ADVERSE REACTIONS sections of the LESCOL and LESCOL XL package insert.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted May 20, 2003) (copy enclosed).

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may 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. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 20-261/S-033, NDA 21-192/S-005." Approval of these submissions by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for these products. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

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

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), 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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Margaret Simoneau, R.Ph., Regulatory Project Manager, at (301) 827-6411.

Sincerely,

{See appended electronic signature page}

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

David Orloff

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