DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-261/S-037
NDA 21-192/S-012

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 November 7, 2005, received November 9, 2005, 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 January 18 and March 22 (email), 2006.

These "Changes Being Effected" supplemental new drug applications provide for changes to the **PRECAUTIONS**, Drug Interactions subsection and to the **DOSAGE AND ADMINISTRATION** section of the package insert.

To the **PRECAUTIONS**, Drug Interactions subsection, a new "Fluconazole" paragraph was added to read:

> Administration of fluvastatin 40 mg single dose to healthy volunteers pre-treated with fluconazole for 4 days results in an increase of fluvastatin C_{max} (44%) and AUC (84%). Based on this data, caution should be exercised when fluvastatin is co-administered with fluconazole.

To the **DOSAGE AND ADMINISTRATION** section, a new last sentence to the second paragraph was added to read:

> Do not break, crush or chew Lescol XL tablets or open Lescol capsules prior to administration.

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 March 22 (email), 2006] (copy enclosed).

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions "**FPL for approved supplement NDA 20-261/S-037, NDA 21-192/S-012**." 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 product. 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:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705-1266

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
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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, M.S.,R.Ph., Regulatory Project Manager, at (301) 796-1295.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, M.D.
Acting Director
Division of Metabolism and Endocrinology 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/

Eric Colman
3/22/2006 02:03:38 PM
Acting Deputy Director