DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-261/S-035, S-036
NDA 21-192/S-010, S-011

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 June 15, 2005, received June 16, 2005, for NDA's 20-261/S-035, 21-192/S-010, and NDA's 20-261/S-036 and 21-192/S-011 dated October 14, 2005, received October 17, 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 October 14, 2005, February 6, March 27 (email), April 4, and April 7 (email), 2006.

The supplemental new drug applications for NDA's 20-261/S-035 and 21-192/S-010 provide for revising the **DOSAGE AND ADMINISTRATION** section of the package insert to recommend that the Lescol 80 mg XL tablet dose may be taken at any time of the day instead of in the evening.

The supplemental new drug applications for NDA's 20-261/S-036 and 21-192/S-011 provide for the addition of an indication for the treatment of heterozygous familial hypercholesterolemia in adolescent boys and postmenarchal girls, ages 10 to 16 years, with a recommended dosing range of Lescol capsules 20 to 40 mg twice daily or Lescol XL 80 mg tablet once daily. These supplemental applications respond to our Written Request of December 4, 2001, as amended July 15, 2002.

These supplemental new drug applications additionally provide the same updated information in the patient package insert (PPI).

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 27 (email), 2006, and PPI submitted April 7 (email), 2006](copies 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-035, S-036 and NDA 21-192/S-010, S-011**." Approval of these submissions by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement to address the dosing regimen of the XL tablet.

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
4/10/2006 12:20:06 PM
Acting Deputy Division Director