DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 21-316/S-010

Andrx Laboratories, Inc.
Attention: Josephine Cucchiaro, Ph.D.
Vice President, Clinical Research and Regulatory Affairs
411 Hackensack Ave, 3rd Floor
Hackensack, NJ 07601

Dear Dr. Cucchiaro:

Please refer to your supplemental new drug application dated June 3, 2003, received June 4, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Altoprev™ (lovastatin) Extended Release Tablets, 10 mg, 20 mg, 40 mg, and 60 mg.

We acknowledge receipt of your submissions dated April 23, and June 2, 2004. Your April 23, 2004, submission constituted a complete response to our January 13, 2004, action letter.

This supplemental new drug application provides for labeling changes to the following sections of the package insert:

Proprietary trade name changed to "ALTOPREV" (as approved in S-005)
DESCRIPTION (inactive ingredients)
WARNINGS section, *Myopathy/Rhabdomyolysis* subsection
PRECAUTIONS section, *Geriatric Use* subsection
DOSAGE AND ADMINISTRATION, second paragraph
DOSAGE AND ADMINISTRATION, *Elderly Patients or Patients with Complicated Medical Conditions* subsection and *Dosage in Patients Taking Amiodarone or Verapamil* subsection
HOW SUPPLIED, NDC numbers
Manufactured by Andrx Pharmaceuticals, Inc., Fort Lauderdale, FL 33314 (added)
Revision Date: 05/04

We completed our review of this application, as amended. This application is 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 enclosed labeling (text for the package insert, submitted June 2, 2004).

Please submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – NDA's*. 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 15 of the copies on heavy-weight paper or similar material. For administrative

purposes, this submission should be designated "FPL for approved supplement NDA 21-316/S-010." Approval of this submission by FDA is not required before the labeling is used.

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, HFD-410
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 Valerie Jimenez, Regulatory Project Manager, at (301) 827-9090.

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

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Mary Parks
7/21/04 09:26:16 AM
for Dr. Orloff