DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-316/S-018

Andrx, Labs, LLC
Attention: Kemi Onayemi, PhD
Specialist, Regulatory Affairs
4955 Orange Drive
Fort Lauderdale, FL 33314

Dear Dr. Onayemi:

Please refer to your supplemental new drug application dated November 16, 2006, received November 17, 2006, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Altoprev (lovastatin) Extended-Release Tablets, 10 mg, 20 mg, 40mg and 60 mg.

We acknowledge receipt of your submission dated November 29, 2006.

This "Changes Being Effected" supplemental new drug application provides for the deletion of the 10 mg tablets, and associated labeling revisions to the package insert.

We completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on November 16, 2006.

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Kati Johnson, Regulatory Project Manager, at (301) 796-1234.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, MD
Director
Division of Metabolism and Endocrinology Products
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/

Eric Colman
2/1/2007 07:20:55 AM
Eric Colman for Mary Parks