DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 21-316/S-005

Andrx Laboratories, Inc.
Attention: Nicholas Farina, Ph.D.
Vice President, Regulatory Affairs
401 Hackensack Avenue, 9th Floor
Hackensack, NJ 07601

Dear Dr. Farina:

Please refer to your supplemental new drug application dated December 5, 2002, received December 6, 2002, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Altocor (lovastatin) Extended Release Tablets, 10 mg, 20 mg, 40 mg, and 60 mg.

This supplemental new drug application proposed three alternate proprietary names. The proprietary name, Altoprev, is acceptable.

Your supplement did not include draft labeling. Therefore, you must incorporate the new proprietary name in the currently approved labeling.

We completed our review of your application. This application is approved, effective on the date of this letter, for use as recommended in the agreed upon labeling and with the revision of the proprietary name indicated above.

The final printed labeling (FPL) must be identical, and include the revision of the proprietary name, Altoprev, to all of your currently approved labeling. This is a term of the approval of this application.

- Revised labeling based on the currently approved labeling with the approved brand name. According to our records, the currently approved labeling is the following:

		Submission Date	
• Package Insert	Identifier: 7199, Rev. 09/02	Dec. 6, 2002	S-001
• Container Labels			
30-Count/10 mg	Identifier: 7184 (02/02)	July 1, 2002	NDA
30-Count/20 mg	Identifier: 7188 (02/02)	July 1, 2002	NDA
30-Count/40 mg	Identifier: 7192 (02/02)	July 1, 2002	NDA
30-Count/60 mg	Identifier: 7196 (02/02)	July 1, 2002	NDA
• Professional Sample			
7-Count/60 mg	Identifier: 7195 (02/02)	July 1, 2002	NDA
• Carton			
7-Count/60 mg	No Identifier	July 1, 2002	NDA

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-005." 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 New Drugs
Office of Drug Evaluation II

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
8/20/03 02:47:55 PM
Eric Colman for David Orloff