DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-316/S-001

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

Dear Dr. Farina:

Please refer to your supplemental new drug application dated March 30, 2001, received March 30, 2001, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Altocor (lovastatin) Extended-Release Tablets.

We acknowledge receipt of your submissions dated August 7 (2) and 20, 2002. Your submission of July 12, 2002, constituted a complete response to our July 2, 2002, action letter.

This supplemental new drug application provides for the use of Altocor (lovastatin) Extended-Release Tablets in the primary prevention of coronary heart disease in patients who have average to moderately elevated Total-C and LDL-C and below average HDL-C.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the enclosed labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

We have also restored the reference to the data from the Asymptomatic Carotid Artery Progression Study (ACAPS) in the **CLINICAL PHARMACOLOGY, Pharmacokinetics and Drug Metabolism** section of the labeling text, which was inadvertently omitted from the NDA approval.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted August 20, 2002).

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. Please individually mount ten 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-001." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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 William C. Koch, R.Ph., Regulatory Project Manager, at (301) 827-6412.

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/

David Orloff

9/11/02 05:59:23 PM