DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-316

Aura 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 new drug application (NDA) 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, 10 mg, 20 mg, 40 mg, 60 mg.

We acknowledge receipt of your submissions dated May 1, 17, and 28, 2002. Your submission of May 1, 2002, constituted a complete response to our April 18, 2002, action letter.

This new drug application provides for the use of Altocor, an extended release formulation of lovastatin, for lowering total cholesterol and LDL-C to target levels as an adjunct to diet and exercise, to slow the progression of atherosclerosis in patients with coronary heart disease, and to reduce Total-C, LDL-C, Apo B and triglycerides and to increase HDL-C in patients with Fredrickson types IIa and IIb dyslipoproteinemia.

We have completed the review of this 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 agreed upon labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted February 18, 2002, immediate container and carton labels submitted May 17, 2002). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 NDA 21-316." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your postmarketing study commitments in your submissions dated May 1 and 28, 2002. These commitments are listed below.

1. Commitment/Study Description: A drug interaction study comparing the pharmacokinetics of both lovastatin and lovastatin acid with and without concomitant antacid.

   Commitment Category: Biopharmaceutics

   Protocol Submission: The Division recommends that a draft protocol for this study be submitted to the application for review and comment and that the protocol not be initiated until comments have been communicated.

   Final Report Submission: within 12 months of final approval.

2. Commitment/Study Description: An analysis for percent water content and residual solvent using the methods in STM AR-013 for at least the first three commercial drug product lots of each strength in order to revise or maintain the acceptance criteria submitted as a "Changes Being Effected in 30 Days" supplement.

   Commitment Category: Chemistry, Manufacturing and Controls

   Final Report Submission: within three months of final approval.

3. Commitment/Study Description: Establishment of in-process weight increase specifications for the seal, enteric and sustained release coating process steps based on three post-approval commercial drug product lots of each strength submitted as a "Changes Being Effected in 30 Days" supplement. This commitment also provides for increased sampling for dissolution testing on all lots released for marketing in the interim.

   Commitment Category: Chemistry, Manufacturing and Controls

   Final Report Submission: within three months of final approval.

Submit protocols for requested studies and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "**Postmarketing Study Protocol", "Postmarketing Study Final Report", or "Postmarketing Study Correspondence."**

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Be advised that, as of April 1, 1999, 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 (63 *FR* 66632). We are waiving the pediatric study requirement for this application for patients <10 years old and deferring submission of pediatric studies for patients 10-17 years old. If we determine that pediatric studies are necessary, we will specify a date by which you must submit the required assessments.

In addition, submit three copies of the introductory promotional materials that you propose to use for this 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:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
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

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

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