DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21249/S-026

**SUPPLEMENT APPROVAL**

Abbott Laboratories
Attention: Jean Conaway
Associate Director, Global Pharmaceutical Regulatory Affairs
200 Abbott Park Road
Dept. PA76, AP30
Abbott Park, IL 60064

Dear Ms. Conaway:

Please refer to your Supplemental New Drug Application (sNDA) dated November 5, 2010, received November 8, 2010, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for ADVICOR (niacin extended release/lovastatin) Tablets, 500 mg/20 mg, 750 mg/20 mg, 1000 mg/20 mg, and 1000 mg/40 mg.

We acknowledge receipt of your amendment dated December 27, 2010.

This "Changes Being Effected" supplemental new drug application provides for revision to the ADVERSE REACTIONS section, postmarketing events subsection of the package insert to align it with the Mevacor labeling for the lovastatin component of ADVICOR. Specifically, the following adverse reactions are being added: depression, peripheral nerve palsy, dermatomyositis, progression of cataracts. The application also provides for the addition of the statement "See also the full prescribing information for niacin extended release (Niaspan) and lovastatin products."

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

## CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling (text for the package insert) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements and any annual reportable changes not included in the enclosed labeling. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at

http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.
Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format that includes the changes approved in this supplemental application.

**LETTERS TO HEALTH CARE PROFESSIONALS**

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

**REPORTING REQUIREMENTS**

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

Sincerely,

*{See appended electronic signature page}*

Eric Colman, MD
Deputy Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE: Content of Labeling

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

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/s/

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ERIC C COLMAN
01/24/2011