DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21249/S-024 **SUPPLEMENT APPROVAL**

Abbott Laboratories
Attention: Michael J. Walters
Regulatory Affairs Manager, CMC
Global Regulatory Affairs
Dept PA71/Bldg. AP30-1E
200 Abbott Park Road
Abbott Park, IL 60064-6157

Dear Mr. Walters:

Please refer to your October 16, 2009 Supplemental New Drug Application (sNDA), received October 19, 2009, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Advicor (niacin/lovastatin), 500 mg/20 mg, 750 mg/20 mg, 1000 mg/20 mg, 1000 mg/40 mg.

We acknowledge receipt of your submissions dated October 27, 2009.

This "Prior Approval" supplemental new drug application provides for a new site of tablet manufacture (Abbott Pharmaceuticals PR, Ltd. [APL] Barceloneta, Puerto Rico), tablet coating and final product printing, and manufacturing process changes including the removal of the tablet debossing.

We have completed our review of this 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, please submit the content of labeling [21 CFR 314.50(1)(l)(i) in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.htm that is identical to the enclosed labeling (text for the package insert, Quick Answers for Patients). For administrative purposes, please designate this submission, "**SPL for approved NDA 21249/S-024**".

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005).*

Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 21249/S-024**." Approval of this submission by FDA is not required before the labeling is used.

LETTERS TO HEALTH CARE PROFESSIONALS

If you 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 an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

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 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
Commercial Bottle Labels (90-count):
- -500 mg/20 mg
- -750 mg/20 mg
- -1000 mg/20 mg
- -1000 mg/40 mg

Sample labeling (500 mg/20 mg):
- -Blister (3 tablets)
- -Carton (Sample pack)
- -Tray
- -Quick Answers for Patients ("Tips Card")

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21249	SUPPL-24	ABBOTT LABORATORIES	ADVICOR (NIACIN ER/LOVASTATIN)

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

/s/

AMY G EGAN
03/31/2010
Amy Egan for Eric Colman