DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22078/S-008

SUPPLEMENT APPROVAL

Abbott Laboratories
Attention: Sharon Graham
Regulatory Affairs Manager, CMC, Global Pharmaceutical Regulatory Affairs
200 Abbott Park Road
Abbott Park, IL 60064

Dear Ms. Graham:

Please refer to your Supplemental New Drug Application (sNDA) dated May 21, 2010, received May 21, 2010, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Simcor (Niacin ER/Simvastatin) Tablets.

We acknowledge receipt of your amendment dated July 30, 2010, containing revised labeling.

This "Changes Being Effected" supplemental new drug application provides for a new 7-count sample presentation for the 500/20 strength product that will replace the currently approved 3-count sample. The application also includes bottle labeling for the 3-count sample that contained annual reportable revisions that were approved in Supplements -006 and -007 on July 28, 2010.

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.

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 (June 2008)." 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 "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 22078/S-008**." Approval of this submission by FDA is not required before the labeling is used.

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

ENCLOSURES:
3-count sample bottle label
7-count sample bottle label
7-count sample carton

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

/s/

ERIC C COLMAN
12/22/2010