DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22078/S-006, S-007 **SUPPLEMENT APPROVAL**

Abbott Laboratories
Attention: Tracy Verciglio
Associate Director, Regulatory Affairs, CMC
Dept. PA71, Bldg. AP30-1E
200 Abbott Park Road
Abbott Park, IL 60064-6157

Dear Ms. Verciglio:

Please refer to your Supplemental New Drug Applications (sNDAs) dated September 30, 2009 (S-006) and November 20, 2009 (S-007), received September 30, 2009 (S-006) and November 20, 2009 (S-007), submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for SIMCOR (Niacin ER/Simvastatin) Tablets, 500 mg/20 mg, 750 mg/20 mg, and 1000 mg/20 mg.

We acknowledge receipt of the following submissions to Supplement -007:
-December 17, 2009
-February 5, 2010
-June 29, 2010

These "Prior Approval" supplemental new drug applications provides for the following:
Supplement -006:

1. The Abbott Pharmaceuticals PR, Ltd (APL) site in Barceloneta, PR as a new manufacturing site for the Niacin Extended-Release (ER) core tablet and the final core tablet.;
2. Removal of the tablet debossing and the addition of the black printing.;
3. The Abbott Pharmaceuticals PR, Ltd (APL) site in Barceloneta, PR as an analytical testing site for the drug substance niacin.;
4. Removal of the following drug substance niacin analytical testing sites: (b) (4)
5. Removal of (b) (4) as a manufacturer of the drug substance simvastatin.;
6. Removal of the following drug substance simvastatin analytical testing sites: (b) (4)
7. The removal of (b) (4) as a drug product manufacturing and testing site.;

8. The removal to the two (b) (4) packaging sites for the drug product.;
9. The removal of the (b) (4) as a drug product analytical testing site.; and
10. Revision of the drug product Physical Examination Specification acceptance criteria to support the non-debossed, printed tablet.
11. Associated labeling revisions.

Supplement -007:

1. Addition of two dosage strengths: 500 mg/40 mg and 1000 mg/40 mg;
2. Reformulation of the 1000 mg/20 mg tablet to utilize a 1000 mg niacin ER (b) (4)
3. The Abbott Pharmaceuticals PR, Ltd (APL) site in Barceloneta, PR as a new manufacturing site for the Niacin Extended-Release (ER) core tablet and for the final product printing.;
4. Removal of the tablet debossing and the addition of white printing.;
5. The Abbott Pharmaceuticals PR, Ltd (APL) site in Barceloneta, PR as an analytical testing site for niacin. USP.
6. Associated labeling revisions.

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.

For future bioequivalence studies for the 500 mg/20 mg strength tablet, we recommend using 1000 mg/40 mg (2 X 500 mg/20 mg) instead of the 2000 mg/80 mg dose.

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. 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 pending "Changes Being Effected" (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.

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 22078/S-006, S-007**" Approval of this submission by FDA is not required before the labeling is used.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

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 CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch
Food and Drug Administration
Suite 12B-05
5600 Fishers Lane
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, Regulatory Project Manager, at (301) 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:
- Content of Labeling: Package Insert
- Carton and Container Labeling:
  - 500 mg/20 mg, 3-count sample carton
  - 500 mg/40 mg, 7-count sample bottle label
  - 500 mg/40 mg, 7-count sample carton label
  - Quick Answers for Patients (“Tips Card”)
  - 500 mg/40 mg, 90-count bottle label
  - 500 mg/20 mg, 90-count bottle label
  - 750 mg/20 mg, 90-count bottle label
  - 1000 mg/20 mg, 90-count bottle label
  - 1000 mg/40 mg, 90-count bottle label

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22078	SUPPL-7	ABBOTT LABORATORIES	SIMCOR
NDA-22078	SUPPL-6	ABBOTT LABORATORIES	SIMCOR

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/s/

ERIC C COLMAN
07/28/2010