



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-078/S-002

Abbott Laboratories
Attention: David C. Ross, Pharm.D.
Director, Global Regulatory Affairs
200 Abbott Park Road
Abbott Park, IL 60064-6188

Dear Dr. Ross:

Please refer to your supplemental new drug application dated April 24, 2008, received April 24, 2008, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Simcor (niacin extended release/simvastatin) Tablets, 500 mg/20 mg, 750 mg/20 mg, and 1000 mg/20mg.

This supplemental new drug application provides for revision to the first sentence of the ADVERSE REACTIONS-Overview section of the package insert to include the underlined text that was inadvertently not included when the initial NDA was approved. The statement now reads, "In a controlled clinical study, 14% of patients randomized to SIMCOR discontinued therapy due to an adverse event."

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

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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}

Mary H. Parks, M.D.
Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: Package Insert

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

/s/

Eric Colman
7/24/2008 09:22:32 AM
Eric Colman for Mary Parks