# CENTER FOR DRUG EVALUATION AND RESEARCH

*APPLICATION NUMBER:*

**NDA 22-078**

# APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-078

**NDA APPROVAL**

Abbott Laboratories
Attention: David C. Ross, Pharm.D., MBA
Director, Global Pharmaceutical Regulatory Affairs
200 Abbott Park Road
Abbott Park, IL 60064-6157

Dear Dr. Ross:

Please refer to your new drug application (NDA) dated April 17, 2007, received April 17, 2007, 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/20 mg.

We acknowledge receipt of your submissions dated August 10, 13 and 22, September 25, October 12, November 8 and 19, 2007, and January 30, 2008.

This new drug application provides for the use of Simcor (niacin extended-release/simvastatin) Tablets to:

1. Reduce elevated total–C, LDL-C, Apo B, non-HDL-C, TG, or to increase HDL-C in patients with primary hypercholesterolemia and mixed dyslipidemia when treatment with simvastatin monotherapy or niacin extended-release monotherapy is considered inadequate.
2. Reduce TG in patients with hypertriglyceridemia (Fredrickson type IV hyperlipidemia) when treatment with simvastatin monotherapy or niacin extended-release monotherapy is considered inadequate.

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.

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

## 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(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert). Upon receipt, we will transmit that version to the National Library of

Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 22-078."

With regard to the "Quick Answers for Patients" (Tips card) that is distributed with the professional sample container, the labeling must be identical to that submitted January 30, 2008, revised as follows:

1. Add the following section:

What Is SIMCOR Used For?

* -SIMCOR is the combination of two cholesterol-lowering medications: niacin extended-release (NIASPAN®) and simvastatin. SIMCOR is used along with diet to lower levels of cholesterol, LDL "bad" cholesterol, and triglycerides and to increase HDL "good" cholesterol.
* -SIMCOR has not been shown to lower the risk of heart attacks or death any more than simvastatin or niacin when they are used alone.

2. Under the header "When Taking SIMCOR..." add the underlined text below:
• -You should take SIMCOR every night with a low-fat snack at bedtime as prescribed. If you miss a dose, take your usual SIMCOR dose the next evening; do not make up for missed doses by taking extra tablets.
• -SIMCOR should not be used if you have liver problems, stomach ulcers, or serious bleeding problems.

3. Under the header "Other Important Information" add the underlined text below:
-Muscle pain, muscle weakness, or muscle tenderness can be a sign of a serious but rare muscle disorder, from which rare cases of death have occurred. Report any of these symptoms to your doctor immediately.

4. Under the header "What is Flushing?" revise the text to read as follows:
• -Flushing may subside after several weeks of consistent SIMCOR use.

**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 22-078.**" Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

**PEDIATRIC RESEARCH EQUITY ACT (PREA)**

All applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable. We are waiving the pediatric study requirement for this application because the drug does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients and is not likely to be used in a substantial number of pediatric patients.

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 www.fda.gov/cder/ddmac.

In addition, we request that you submit one copy of the introductory promotional materials you propose to use for this product to this division.

**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
HFD-001, Suite 5100
5515 Security Lane
Rockville, MD 20852

**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}*

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

Enclosure: Package Insert
SIMCOR 500 mg/20 mg-sample bottle label (3 tablets)
SIMCOR 500 mg/20 mg-sample carton (3 tablets)
SIMCOR 500 mg/20 mg-90-count bottle
SIMCOR 750 mg/20 mg-90-count bottle
SIMCOR 1000 mg/20 mg-90-count bottle

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

/s/
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Eric Colman
2/15/2008 01:20:19 PM
Eric Colman for Mary Parks