DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

NDA 20-381/S-038

Abbott Laboratories
Attention: Jean M. Conaway, R.Ph.
Associate Director, Dyslipidemia
200 Abbott Park Road
Abbott Park, Il 60064-6188

SUPPLEMENT APPROVAL

Dear Ms. Conaway:

Please refer to your supplemental new drug application dated August 19, 2008, received August 20, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Niaspan (niacin extended release tablets).

We acknowledge receipt of your submission dated November 21, 2008.

This supplemental new drug application provides for the following revisions to the package insert:
-convert to PLR format
-add some postmarketing adverse events
-add text approved under NDA 22-078 (Simcor [extended release niacin/simvastatin]) on February 15, 2008.
The supplement also revises the Niaspan Tips Card (Quick Answers for Patients) that is provided with the sample package.

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, Quick Answers for Patients). 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 20-381/S-038**."

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

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, 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
Quick Answers for Patients

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
3/26/2009 12:36:44 PM
Eric Colman for Mary Parks