DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-381/S-034

Abbott Laboratories
Attention: Natalie Tolli
Associate Director, Dyslipidemia
Dept. PA76, Building AP30-1NE
200 Abbott Park Road
Abbott Park, IL 60064-6157

Dear Ms. Tolli:

Please refer to your supplemental new drug application dated June 15, 2007, received June 18, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Niaspan (niacin extended-release tablets).

This supplemental new drug application provides for modification of the DOSAGE AND ADMINISTRATION section of the package insert to remove concomitant use of Niaspan with lovastatin as second line therapy. This change was necessitated by the approval of Advicor (NDA 21-249) Supplement -015 on April 6, 2007.

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 and with the minor editorial revisions listed below.

Please replace "hs" throughout the labeling with "at bedtime".

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, except for including the revisions listed, the enclosed labeling (text for the package insert). These revisions are terms of the NDA approval. 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 supplemental NDA 20-381/S-034."

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

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 & 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
12/18/2007 07:16:58 AM
Eric Colman for Mary Parks