DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-381/S-027

Abbott Laboratories, Inc.
Attention: Jeanne Fox
Senior Director, Regulatory Affairs
200 Abbott Park Road
Abbott Park, IL 60064-6157

Dear Ms. Fox:

Please refer to your supplemental new drug application dated June 29, 2006, received June 30, 2006, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Niaspan (niacin extended-release tablets).

We acknowledge receipt of your submissions dated November 21, 2006, and January 11, 2007.

Your submission of January 11, 2007 constituted a complete response to our November 15, 2006 action letter.

This supplemental new drug application provides for the addition of a film coating to the tablets.

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

1. The circular graphic will be removed from the bottle labels, sample blister labeling, sample carton, and "Quick Answers for Patients" (Patient tips card) pamphlet distributed with the sample package.
2. The name of the drug will be remain "Niaspan (niacin extended-release tablets)".

The final printed labeling (FPL) must be identical, and include the revisions indicated, to the enclosed labeling submitted November 8, 2006. These revisions are terms of the approval of this application.

Submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for posting on the DailyMed website.

Please submit either an electronic version or 20 paper copies of the FPL as soon as it is available (no more than 30 days after it is printed). If paper copies are submitted, individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-381/S-027**." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly 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

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
Bottle Labels (100 count): 500 mg, 750 mg, 1000 mg
Sample blister label, 500 mg
Sample carton, 500 mg.
"Quick Answers for Patients" (Patient tips card) pamphlet

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

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Eric Colman for Mary Parks