DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20381/S-039, S-041 **APPROVAL LETTER**

Abbott Laboratories
Attention: Michael J. Walters
Regulatory Affairs Manager, CMC
Global Pharmaceutical Regulatory Affairs
200 Abbott Park Road
Abbott Park, IL 60064

Dear Mr. Walters:

Please refer to the following supplemental new drug applications submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Niaspan (extended-release niacin) Tablets, 500 mg, 750 mg, and 1000 mg:

Supplement -039, a prior approval application, was submitted January 29, 2009, and received January 30, 2009. This supplement provides for an alternate tablet manufacturing site [APL, in addition to the currently approved Abbott site in Edison, NJ], a new manufacturing site for final product printing (Abbott Park, IL), and manufacturing process changes including the removal of the tablet debossing (all strength tablets), and associated package insert and bottle label revisions.

Supplement -041, a prior approval application, was submitted March 12, 2009, and received March 13, 2009. This supplement provides for the removal of tablet debossing from 500 mg. Niacin Tablets manufactured at Norwich Pharmaceuticals, Inc., Norwich, NY and associated package insert revisions.

We acknowledge receipt of your submissions dated May 15, 2009 (both S-039 and S-041), July 2, 2009 (S-041), and September 3, 2009 (S-039).

We completed our review of these supplemental new drug applications, as amended. These supplements are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed upon labeling text, which is identical to the content of labeling [21 CFR 314.50(1)(1)(i)] in structured product labeling (SPL) format submitted on May 15, 2009.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed 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 Container Labels for approved NDA 20381/S-039, S-041**." Approval of this submission by FDA is not required before the labeling is used.

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 the requirements for an approved NDA set forth under 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}

Eric Colman, M.D.
Deputy Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: Package Insert
Bottle Labels:
500 mg, 90-count (tablets manufactured at Norwich, NY)
500 mg, 90-count (tablets manufactured at Barceloneta, PR)
750 mg, 90-count (tablets manufactured at Barceloneta, PR)
1000 mg, 90-count (tablets manufactured at Barceloneta, PR)

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20381	SUPPL-39	ABBOTT LABORATORIES	NIASPAN (NIACIN) SR TABLETS
NDA-20381	SUPPL-41	ABBOTT LABORATORIES	NIASPAN (NIACIN) SR TABLETS

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

/s/

ERIC C COLMAN
09/16/2009