



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20381/S-042

SUPPLEMENT APPROVAL

Abbott Laboratories
Attention: Jean Conaway
Associate Director, Global Pharmaceutical Regulatory Affairs
Department RA76/Building AP30-1E
200 Abbott Park Road
Abbott Park, IL 60064

Dear Ms. Conaway:

Please refer to your supplemental new drug application dated September 29, 2009, received September 29, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Niaspan (niacin extended release) Tablets.

This "Prior Approval" supplemental new drug application provides for the addition of the postmarketing adverse event "burning sensation/skin burning sensation" to section 6 of the package insert.

We have completed our review of this application. It is 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(l)(1)(i)] in structured product labeling (SPL) format submitted on September 29, 2009.

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, 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: Content of Labeling

Application
Type/Number

Submission
Type/Number

Submitter Name

Product Name

NDA-20381

SUPPL-42

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
02/24/2010