DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

NDA 21402/S-020

SUPPLEMENT APPROVAL

Abbott Laboratories
Attention: Patrick L. Carney, Manager
Global Pharmaceutical Regulatory Affairs CMC
Dept. PA71/Bldg. AP30-1E
200 Abbott Park Road
Abbott Park, IL 60064-6157

Dear Mr. Carney:

Please refer to your supplemental new drug application (sNDA) dated September 30, 2009, received September 30, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Synthroid (levothyroxine sodium) Tablets, for all strengths: 25, 50, 75, 88, 100, 112, 125, 137, 150, 175, 200, and 300 mcg.

We acknowledge receipt of your amendment dated July 16, 2010.

The July 16, 2010, submission constituted a complete response to our February 26, 2010, action letter and included the following changes:

This "Prior Approval" supplemental new drug application provides for standardized drug product immediate container (bottle) and carton labels with the following changes:

- Carton labels (Abbo-Pac) – improved legibility and size of the established name, enlarged the strength and de-emphasized the statement of the number of units in the containers.

- Container (bottle) labels - improved legibility and size of the established name, enlarged the strength and de-emphasized the statement of the number of units in the containers, enlarged a color block that mimics the tablet color, and adds a tablet image to the label.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your July 16, 2010, submission containing final printed carton and container labels.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to 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, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

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 Linda Galgay, Regulatory Project Manager, at (301) 796-5383.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, MD
Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURES:
Carton and Container Labeling

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

/s/

MARY H PARKS
01/14/2011