DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

NDA 21-292/S-002

ICON Development Solutions
Attention: Young Choi
Manager, Regulatory Affairs
U.S. Agent for Merck KGaA
6031 University Blvd.
Ellicott City, MD 21043

Dear Mr. Choi:

Please refer to your supplemental new drug application dated October 9, 2008, received October 14, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Novothyrox (levothyroxine sodium) Tablets.

We acknowledge receipt of your submissions dated October 31, 2008, and March 10, 2009.

This "Changes Being Effected" supplemental new drug application provides for the following changes to the package insert:

1. Addition of a statement under the PRECAUTIONS section that agents such as iron and calcium supplements and antacids can decrease the absorption of levothyroxine tablets. This addition was requested in a supplement request letter dated June 10, 2005.

2. Addition of a statement under the PRECAUTIONS section with instructions for reporting side effects to FDA.

3. Addition of information under the PRECAUTIONS section regarding drug-drug interaction between levothyroxine and orlistat. This addition was requested in a supplement request letter dated September 28, 2007.

We have 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.

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 the enclosed labeling (text for the package insert, submitted March 10, 2009**)**. 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 NDA 21-292/S-002."

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
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 Julie Marchick, Regulatory Project Manager, at (301) 796-1280.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, M.D.
Director
Division of Metabolism and 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/

Mary Parks

3/26/2009 12:14:28 PM