DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-301/S-026

King Pharmaceuticals, Inc.
Attention: Karen Baker
Senior Manager Regulatory Affairs
501 Fifth Street
Bristol, Tennessee 37620

Dear Ms. Baker:

Please refer to your supplemental new drug application dated March 27, 2008, received March 28, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Levoxyl (levothyroxine sodium) Tablets.

We also refer to our supplement request letter dated September 28, 2007, in which you were asked to add information to the package insert regarding interaction between orlistat and levothyroxine.

This "Changes Being Effected" supplemental new drug application provides for the addition of the information requested in our supplement request letter dated September 28, 2007.

We have completed our review of this application. 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 and the patient package insert submitted March 27, 2008), with the following changes:

1. Underline the heading "Secondary (pituitary) and tertiary (hypothalamic) hypothyroidism" under the Laboratory Tests subsection of the PRECATIONS section.
2. Underline the heading "General" under the Pediatric Use subsection of the PRECAUTIONS section.

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 21-301/S-026."

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

7/8/2008 01:21:39 PM