DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-301/S-014

Jones Pharma, a wholly owned subsidiary of King Pharmaceuticals, Inc.
Attention: Karen Baker
Manager, Regulatory Affairs
501 Fifth Street
Bristol, TN 37620

Dear Ms. Baker

Please refer to your supplemental new drug application dated September 16, 2004, received September 17, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Levoxyl (levothyroxine sodium) Tablets, USP.

We acknowledge receipt of your electronic submission dated October 4, 2004.

This "Changes Being Effected" supplemental new drug application provides for labeling changes to the package insert to advise that the tablets must be taken with a full glass of water. The new information was added to the **PRECAUTIONS** ("Information for Patients" subsection), **ADVERSE REACTIONS**, and **DOSAGE AND ADMINISTRATION** sections of the package insert.

A "Dear Health Care Provider" letter was included with this submission.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the enclosed final printed labeling (FPL) submitted on October 4, 2004.

We note that a sentence was added in the **STORAGE CONDITIONS** section stating "Meets USP Dissolution Tests 1 and 2". This sentence should be deleted in the next printing and the revised labeling submitted in the next annual report.

We would like to clarify terminology regarding types of labeling. The revisions contained in this supplement were made to the package insert (PI). However, you referred to the "Physician's Package Insert and Patient Information" as PI. For your information, the package insert may also be referred to as the prescribing information, the physician insert, or the physician information. Some products also have another piece of labeling called the patient package insert (PPI) that is written specifically for patients in an easy to understand format.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send two copies of both the promotional materials and the package inserts directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Holly Wieland, Regulatory Project Manager, at (301)827-6410.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products HFD-510
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosures:

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

/s/

David Orloff

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