DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug
Administration
Rockville MD 20857

NDA 21-301/S-002

Jones Pharma Inc. (a wholly owned subsidiary of King Pharmaceuticals, Inc.)
Attention: Tom Der
Director, Regulatory Affairs
591 Fifth Street
Bristol, TN 37620

Dear Mr. Der:

Please refer to your supplemental new drug application dated January 24, 2002, received January 25, 2002, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Levoxyl (levothyroxine sodium tablets, USP).

This "Changes Being Effected" supplemental new drug application provides for changes to the package insert requested by the Agency on November 19, 2001. The revisions are listed below:

- **Black Box WARNING**: Adds "**or for weight loss**" after the word "**obesity**" in the first sentence.

- **ADVERSE REACTIONS**: After "**Pseudotumor cerebri"** adds "**and slipped capital femoral epiphysi**s" and follows that sentence with "**Overtreatment may result in craniosynostosis in infants and premature closure of the epiphyses in children with resultant compromised adult height.***"*

- **DOSAGE AND ADMINISTRATION:** Changes the last two sentences to read, **"Therefore, oral thyroid hormone drug products are not recommended to treat this condition. Thyroid hormone products formulated for intravenous administration should be administered."**

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted January 24, 2002). Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
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 Enid Galliers, Chief, Project Management Staff, at (301) 827-6429.

Sincerely,

***{See appended electronic signature page}***

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

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

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/s/

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Mary Parks
7/17/02 10:24:26 AM
for Dr. Orloff