**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 10-379/S-047

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

Dear Mr. Der:

Please refer to your supplemental new drug application dated November 19, 2001, received November 21, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cytomel® (liothyronine tablets), 5 mcg, 25 mcg, 50 mcg.

This supplemental new drug application provides for revisions to the package insert as required by the August 27, 1997 Federal Register Notice entitled, *"Specific Requirements on Content and Format of Labeling for Human Prescription Drugs; Addition of 'Geriatric Use'"* and a change in the distributor information.

1. The following paragraph has been added to the **PRECAUTIONS** section following the "Nursing Mothers" subsection:

   **Geriatric Use**
   *Clinical studies of liothyronine sodium did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy. This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.*

2. The "Manufactured by Schering Canada, Inc. . . . for Jones Pharma Inc." statement has been replaced by the following:

   [Monarch logo]
   *"Manufactured by Schering Canada, Inc. . . ."*
   *"Distributed by: Monarch Pharmaceuticals, Inc, Bristol, TN 37620."*

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 agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted May 10, 2002) for this supplement (ID# 83-481648 Rev. 11/01).

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 10-379/S-047." Approval of this submission by FDA is not required before the labeling is used.

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, HFD-510
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE

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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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David Orloff

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