



NDA 20-105/S-002

Jones Pharma, Inc (a wholly owned subsidiary of King Pharmaceuticals, Inc.)
Attention: Tom W. Der
Director, Regulatory Affairs
501 Fifth Street
Bristol, TN 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 Triostat (liothyronine injection), 10 mcg/mL.

We acknowledge receipt of your submission dated November 29, 2001.

This supplemental new drug application provides for the addition of a Geriatric Use section 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’.*”

In the **PRECAUTIONS** section a “**Geriatric Use**” subsection was added after the “**Nursing Mothers**” section as follows:

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.

We have completed the review of this supplemental application, as amended, 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 and with the minor editorial revision listed below.

Accordingly, the supplemental application is approved effective on the date of this letter.

The boxed warning that appears at the end of the CONTRAINDICATIONS section should be relocated to be the first item in the WARNINGS section.

The final printed labeling (FPL) must be identical, and include the minor editorial revision indicated, to the submitted draft labeling (package insert submitted November 19, 2001). These revisions are terms of the approval of this application.

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 20-105/S-002." 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
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE

**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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