DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-301/S-006

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

Dear Ms. Baker:

Please refer to your supplemental new drug application dated January 22, 2003, received January 23, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Levoxyl® (levothyroxine sodium tablets, USP).

We acknowledge receipt of your submission dated March 13, 2003.

This "Changes Being Effected in 30 days" supplemental new drug application provides for (1) an alternate blister-packaging facility for the drug product (at an additional site at (b)(4)---------- (b)(4)---------- (2) a new configuration (2 X 5 card) for th----------e ---------- 100- tablet unit dose carton for the 2 X 5 blister cards for the following strength tablets: 25, 50, 75, 100, 125, and 150 mcg.

We have completed our review of this supplemental new drug 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. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted labeling (immediate container [2 X 5 blister cards] and carton [10 X {2 X 5 blister cards}, 100-count unit dose] labels submitted March 13, 2003).

Please submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – NDAs*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-301/S-006." Approval of this submission by FDA is not required before the labeling is used.

Although not a requirement for approval of this supplement, we request that you revise the storage conditions from "Store at 20–25°C (66-77°F) with excursions between 15-30°C (59–86°F)" to "***Store at 20–25°C (66-77°F) with excursions permitted between 15-30°C (59–86°F)***" to be consistent with statements in other levothyroxine sodium tablets products. This may be done at the next printing. This change should also be incorporated in the "STORAGE CONDITIONS" section at the end of the package insert. The revised package insert and container labeling should be submitted in the annual report.

In addition, we suggest that you change the text on all bottle labels, cartons, and folders from "SEE ACCOMPANYING DIRECTIONS FOR COMPLETE AND DETAILED INFORMATION" to ***"See package insert for dosage information"*** as recommended at 21 CFR 201.55. This may be done at the next printing or in the next labeling supplement.

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need to submit a "Special Supplement- Changes Being Effected" including the appropriate FPL accompanied by either the appropriate stability data or reference to such data that had been submitted previously.

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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

We also remind you that we have not received the FPL for the packaging listed below, which was approved May 25, 2001. These submissions should be designated "FPL for approved NDA 21-301." Please notify us if you have not yet printed the labeling.

- Physician Samples- (all 12 strengths), 30-count bottles
- Physician Samples - (all 12 strengths), unit dose blister cards of 7 tablets, calendar cards of 7 blisters in a cardboard folder.
- Unit dose blister strips (1 X 10) - (all 12 strengths), for hospital and physician use.
- 100-Count, unit dose blister cartons – (all 12 strengths), to contain 10 strips of 1 X 10 blisters, for hospital and physician use.

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

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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