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March 14, 2001

VIA FEDERAL EXPRESS

John Jenkins, M.D. Acting Director
Division of Metabolism and Endocrine Drug Products (HFD-510)
Document Control Room 14B-19
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

**RE: Amendment to NDA 21-301
Levoxyl (Levothyroxine Sodium Tablets, USP)**

Dear Dr. Jenkins:

JONES PHARMA INCORPORATED is hereby submitting an amendment to our pending New Drug Application (NDA) for Levoxyl (Levothyroxine Sodium Tablets, USP) submitted July 28, 2000. The information submitted in this amendment was requested by the FDA Biopharmaceutics Reviewers, as a result of a teleconference held between FDA and Jones on February 9, 2001.

Dissolution profiles from three lots of each strength were submitted in Section 6.3 of the original NDA. The procedure utilized for the dissolution tests followed the USP 24 monograph which included 0.2% sodium lauryl sulfate (SLS) in the dissolution medium. The FDA Biopharmaceutics Reviewers requested that Jones perform dissolution testing without the SLS in the medium to determine if the SLS is a necessary component. The data from this requested testing are provided as Attachment 1. [REDACTED]

This application consists of a single volume. An archival copy is being filed in a blue folder and a technical review copy is being filed in a red folder. Additionally desk copies are being sent to Mr. Steve McCort (Project Manager, FDA) and Dr. Steve Johnson (FDA Biopharmaceutics Reviewer).

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By this letter, it is certified that a true copy of this amendment (including a copy of FDA application form 356h and a certification that the contents are a true copy of the amendment filed with the Center for Drug Evaluation and Research) was sent to the Kansas City District office of the FDA. This "field copy" was contained in a burgundy folder.

We look forward to the approval of this NDA. Should any additional information be required, please do not hesitate to contact me at (314) 576-6100 ext. 3070.

Sincerely,

JONES PHARMA INCORPORATED
(A wholly owned subsidiary of King Pharmaceuticals, Inc.)

Nancy Cafmeyer

Nancy Cafmeyer
Director, Regulatory Affairs

Enclosure