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December 14, 2000

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

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 following information is included in this amendment.

Additional Information Requested by Dr. David Lewis, Chemistry Reviewer, FDA

- a) Executed batch records for one lot of each strength submitted in the stability section of the NDA
- b) DMF reference letters from the manufacturers of the resin used to manufacture the 38mm closure
- c) Updated stability data

New Information:

- a) Additional Validation Data for the Analytical Method for Impurity Testing (SA-004)

Corrections to Original NDA Submission:

- a) CMC Section: Corrections to the Finished Product Certificate of Release for lot TT24 (50 mcg Tablets) originally submitted on page 000580 of the NDA
- b) Human Pharmacokinetics and Bioavailability Section: For Study 338-04, adverse event information for Subject 13, originally submitted on pages 002055 and 002061 of the NDA, is being updated

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This amendment is being provided to CDER in duplicate: one Archival copy (blue jacket), a CMC Review copy (red jacket) and a Pharmacokinetics Review copy (orange jacket). Please incorporate this information into the application.

Additionally, a Field Copy (burgundy jacket) containing the CMC section has been forwarded to the FDA District office in Maitland, Florida.

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



Nancy Cafmeyer  
Vice President of Regulatory Affairs