





JONES PHARMA INCORPORATED  
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April 6, 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 Dr. David Lewis, FDA Chemistry Reviewer, as a result of teleconferences held between Dr. Lewis and Jones on March 15 and 22, 2001.

Dr. Lewis requested updated stability data from the 6 month test interval for selected batches and packaging sizes of Levoxyl. The requested updated stability data is presented in Attachments 1-3. Dr. Lewis also requested that Jones calculate the projected loss in potency for the 6 and 12 month test intervals for each stability bracket and packaging size of Levoxyl submitted in NDA 21-301. The projection data is presented in Attachments 4-6.

This amendment 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. David Lewis (FDA Chemistry Reviewer).

By this letter, it is certified that a true copy of the amendment (including a copy of FDA application form 356h and a certification that the contents are a true copy of the application 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.

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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.)

A handwritten signature in cursive script that reads "Nancy Cafmeyer".

Nancy Cafmeyer  
Director, Regulatory Affairs