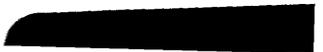




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JONES PHARMA INCORPORATED  
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314 576-6100 Fax 314 469-5749  
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March 19, 2001

**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.

According to the Guidance for Industry – Levothyroxine Sodium Questions and Answers published by the Agency in February 2001, now that an NDA has been approved for levothyroxine sodium tablets and there is a listed drug (Unithroid), applications that have been submitted or filed, but not yet approved, must be amended to contain a patent certification for each patent listed for the listed drug.

By this letter, JONES PHARMA INCORPORATED certifies that in the opinion of and to the best of its knowledge there are no patents that claim the drug or drugs on which investigations that are relied upon in this application were conducted or that claim a use of such drug or drugs

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. 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.

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

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