



May 15, 2001

JONES PHARMA INCORPORATED
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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: Labeling Amendment to NDA 21-301
Levoxyl (Levothyroxine Sodium Tablets, USP)**

Dear Dr. Jenkins:

JONES PHARMA INCORPORATED is hereby submitting a labeling amendment to our pending New Drug Application (NDA) for Levoxyl (Levothyroxine Sodium Tablets, USP) submitted July 28, 2000.

Draft labeling is being submitted for the package insert, container labeling (30, 100 and 1000 count bottles), box label for the 100 and 1000 count bottles and the labeling for the blister packages (both commercial and physician's sample configurations)

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.

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. 33070.

Sincerely,

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

Nancy Cafmeyer
Director, Regulatory Affairs