Jerome Stevens Pharmaceuticals, Inc.

6/13/01

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Dockets Management Branch (HFA 305)
Food and Drug Administration
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

RE: COMMENTS TO [Docket No. 99D-2636] Levothyroxine Sodium

Dear Sir/Madame:

As the holder of the Food and Drug Administrations' Reference Listed drug Unithroid, (Levothyroxine Sodium tablets, USP) we submit the following comments regarding Generic Drug application requirements for this product.

1. **Accelerated Storage Conditions:** As per ICH Guidelines
   6-month storage 40° C; 75%RH (minimum of 3 testing points)
   If any quality parameter is out of specification during the testing period, then an Intermediate Storage condition must be provided in the application.
2. **Intermediate Storage Condition:** As per ICH Guidelines
   12 months at 30° C; 60%RH, testing at 3,6,9 and 12 months.
3. **Long Term Stability:** (controlled room temperature storage as per ICH Guidelines)
   Samples must be stored at 25° C; 60%RH, testing at 3,6,9,12,18 and 24 months; annually thereafter.

- Successful completion of either (1) or (2) must be required for approval. [Will add 6 months expiration to any Long Term data provided]
- Minimum of 12 months storage data required for approval.
- These storage conditions must be required for an applicant to demonstrate quality to Unithroid.
- Product must be formulated to contain NMT 100% of Levothyroxine Sodium at time of release. Levothyroxine Sodium tablets have had a history of potency and stability problems. (See Fed. Reg. August 14, 1997.

Should the agency have questions regarding these comments please contact me at (631) 567-1113.

Sincerely,

Ronald J. Steinlauf

Ronald J. Steinlauf, Vice President
Jerome Stevens Pharmaceuticals, Inc.

Cc: Christine F. Rogers

99D-2636

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60 DaVinci Drive Bohemia NY 11716 Tel: 631-567-1113 Fax 631-567-1189

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