NDA 21-210

Jerome Stevens Pharmaceuticals, Inc.
Attention: Mr. Ronald J. Steinlauf
Vice President
Sixty DaVinci Drive
Bohemia, NY 11716

Dear Mr. Steinlauf:

Please refer to your new drug application (NDA) dated October 19, 1999, received October 21, 1999, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Unithroid (levothyroxine sodium tablets, USP) 25 mcg, 50 mcg, 75 mcg, 88 mcg, 100 mcg, 112 mcg, 125 mcg, 150 mcg, 175 mcg, 200 mcg, and 300 mcg,

We acknowledge receipt of your submissions dated October 28, 1999, and March 22, April 5 (fax), May 3 (fax), June 6, 21, and 29, July 26, and August 8, 9, 11, 15, 17 (1 paper, 1 fax), 18 (2 faxes) and 21 (3 faxes).

This new drug application provides for the use of Unithroid (levothyroxine sodium tablets) for hypothyroidism and suppression of thyroid-stimulating hormone.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed-upon labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the text for the package insert submitted August 21, 2000, and the immediate container labels submitted August 18, 2000, as amended by your August 18 and 21 faxes. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999). For administrative purposes, this submission should be labeled "FPL for approved NDA 21-210." Approval of this submission by FDA is not required before the labeling is used.

We remind you of the postmarketing study commitments specified in your submissions dated July 26 and August 9, 2000.

1. On July 26 you committed to developing, if possible, an improved method for monitoring the degradation product(s) and identifying those degradation products present at levels greater than [ ]%. The new test method and specifications will be included in the stability protocol and submitted to this NDA within one year of the date of this letter.

2. On August 9 you committed to conducting dissolution testing on one lot each of all marketed strengths using the USP 24 monograph. The data will be submitted to this NDA within one year of the date of this letter.

The protocols should be submitted to this NDA. Under 21 CFR 314.81(b)(2)(vii), we request that you include a status summary of your commitments in your annual report to this NDA. The status summary should include expected completion and submission dates, and any changes in plans. For administrative purposes, all submissions relating to these postmarketing study commitments should be clearly labeled **APostmarketing Study Commitment.@**

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Since April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). We note that you have fulfilled the pediatric study requirement at this time.

Please submit one market package of each drug product when available.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Submit two copies of both the promotional materials and the package insert directly to the address below and one desk copy to this division:

Food and Drug Administration
Division of Drug Marketing, Advertising, and Communications, HFD-42
5600 Fishers Lane
Rockville, Maryland 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81

If you have any questions, call Mr. Steve McCort, Regulatory Project Manager, at (301) 827-6415.

Sincerely,

John K. Jenkins, M.D.
Acting Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research