DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-210/S-004

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

Dear Mr. Steinlauf:

Please refer to your supplemental new drug application dated May 21, 2007, received May 24, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Unithroid (levothyroxine sodium tablets, USP).

We acknowledge receipt of your submissions dated October 9, 2007, and February 7, 2008.

Your submission of October 9, 2007, constituted a complete response to our September 24, 2007, action letter.

This supplemental new drug application provides for the addition of the 0.137 mg tablet strength.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

We have not reviewed your February 7, 2008, submission containing the content of labeling in structured product labeling (SPL) format. Upon review, we will contact you if there are any discrepancies between the enclosed package insert (submitted on October 9, 2007) and the content of labeling in SPL format.

Submit final printed container labels that are identical to the enclosed immediate container labels (submitted on October 9, 2007) as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Container Labels for approved NDA 21-210/S-004**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with final printed labeling that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

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

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Julie Marchick, Regulatory Project Manager, at (301) 796-1280.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, M.D.
Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: Package Insert and 0.137 mg Tablet Strength Container Labels

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This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Mary Parks

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