DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-210/S-003

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

Dear Mr. Steinlauf:

Please refer to your supplemental new drug application dated March 26, 2003, received March 27, 2003, 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 August 11 and October 8, 2004.

Your October 8, 2004, submission constituted a complete response to our June 23, 2004, action letter.

This supplemental new drug application proposes to demonstrate bioequivalence between Unithroid and Synthroid in order to obtain an AB rating.

We have determined your Unithroid (levothyroxine sodium tablets, USP) 25, 50, 75, 88, 100, 112, 125, 150, 175, 200, and 300 mcg tablets to be bioequivalent and therapeutically equivalent to the listed drug Synthroid (levothyroxine sodium tablets, USP) 25, 50, 75, 88, 100, 112, 125, 150, 175, 200, and 300 mcg tablets.

Our review concludes that the data establish bioequivalence between these products, and this supplement is approved. However, your supplement requested an "AB" rating for interchangeability between Unithroid and Synthroid. That decision will be made by the Office of Generic Drugs, and any change in the rating of this product will be listed in the next monthly supplement to the "Approved Drug Products with Therapeutic Equivalence Evaluations" list (the "Orange Book") published by the Agency.

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 the Division of Metabolic and Endocrine Drug Products and two copies of both the promotional materials and the package insert directly to:

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

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Holly Wieland, R.N., M.P.H., Regulatory Project Manager, at (301) 827-6410.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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

/s/

David Orloff

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