CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

21-210/S006

Trade Name: Unithroid Tablets

Generic Name: (levothyroxine sodium)

Sponsor: Jerome Stevens Pharmaceuticals, Inc.

Approval Date: July 22, 2009

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APPLICATION NUMBER:

21-210/S006

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APPLICATION NUMBER:

21-210/S006

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 21-210/S-006

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

Dear Mr. Steinlauf:

Please refer to your supplemental new drug application dated March 9, 2009, received March 11, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Unithroid (levothyroxine sodium) Tablets.

This "Changes Being Effected" supplemental new drug application provides for change in potency specifications to 95 – 105 percent, including revised release certification of analysis and stability study specifications.

We completed our review of this supplemental new drug application and it is approved.

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

If you have any questions, call Melissa Fratine, Regulatory Health Project Manager, at (301) 796-4231.

Sincerely,

{See appended electronic signature page}

James D. Vidra, Ph.D.
Branch Chief
Branch VII, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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/s/

Jim Vidra
7/22/2009 05:23:44 PM

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APPLICATION NUMBER:

21-210/S006

CHEMISTRY REVIEW(S)

CHEMISTS REVIEW	1. ORGANIZATION	2. NDA NUMBER
	DMED, HFD-510	21-210
3. NAME AND ADDRESS OF APPLICANT		4. COMMUNICATION, DATE
Jerome Stevens Pharmaceuticals 60 DaVinci Drive Bohemia, NY 11716		S-006, 09-Mar-2009
5. PROPRIETARY NAME	6. NAME OF THE DRUG	7. AMENDMENTS, REPORT, DATE
Unithroid	Levothyroxine Sodium USP	
8. COMMUNICATION PROVIDES FOR:		
A change in the potency specification to 95-105%.		
9. PHARMACOLOGICAL CATEGORY	10. HOW DISPENSED	11. RELATED IND, NDA, DMF
Hypothyroidism	Rx	
12. DOSAGE FORM	13. POTENCY	
Tablet	25, 50, 75, 88, 100, 112, 125, 137, 150, 175, 200, and 300 mcg	
14. CHEMICAL NAME AND STRUCTURE		
See Chemistry Review #1		
15. COMMENTS		
This change constitutes an annual reportable change since (1) the change in a specification is to comply with an official compendium; and, (2) the acceptance criteria for potency is tightened. However, this supplement is in response to a letter from Dr. Moheb Nasr, Director, Office of New Drug Quality Assessment on 03-Oct-2007 notifying all levothyroxine sodium manufacturer's to submit a supplement changing the potency specification from 90-110% to 95-105% of the label claim for Unithroid (levothyroxine sodium) tablets. This supplement includes revised release and stability specifications changing the potency limit to 95-105% of the label claim. There are no changes to the manufacturing process, product formulation or expiration date. The applicant will apply the revised potency limits to batches produced on or after 03-Oct-2009, when the official date of the potency change for Levothyroxine Sodium Tablets in the USP.		
16. CONCLUSION AND RECOMMENDATION		
The applicant has satisfactorily revised the specifications for Levothyroxine sodium to 95-105% of the label claim. Issue an Approval Letter.		
17. NAME	18. REVIEWERS SIGNATURE	19. DATE COMPLETED
JANICE BROWN	See appended electronic signature sheet	01-Jun-2009
DISTRIBUTION: ORIGINAL JACKET CSO REVIEWER DIVISION FILE		

AP

1 Page(s) Withheld

✓ § 552(b)(4) Trade Secret / Confidential

_____ § 552(b)(4) Draft Labeling

_____ § 552(b)(5) Deliberative Process

Withheld Track Number: Chemistry-21-210 S006

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/s/

Janice Brown
6/1/2009 02:04:47 PM
CHEMIST

Eric Duffy
6/1/2009 05:37:04 PM
CHEMIST