CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

21-301/S028

Trade Name: Levoxyl Tablets

Generic Name: (levothyroxine sodium)

Sponsor: King Pharmaceuticals, Inc.

Approval Date: October 6, 2009

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APPLICATION NUMBER:

20-301/S028

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APPLICATION NUMBER:

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APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21-301/S-028

APPROVAL LETTER

King Pharmaceuticals, Inc.
Attention: Felicia Bullock, Senior Director Regulatory Affairs
501 Fifth Street
Bristol, TN 37620

Dear Ms. Bullock:

Please refer to your supplemental new drug application dated October 2, 2009, received October 5, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Levoxyl (levothyroxine sodium) Tablets.

This "Changes Being Effected" supplemental new drug application provides for tightening the potency specification to 95.0 – 105.0%.

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 Teshara G. Bouie, Regulatory Health Project Manager, at (301) 796-1649.

Sincerely,

{See appended electronic signature page}

Eric P. Duffy, Ph.D.
Director
Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21301	SUPPL-28	KING PHARMACEUTICALS INC	LEVOXYL

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/s/

ERIC P DUFFY
10/06/2009

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APPLICATION NUMBER:

20-301/S028

CHEMISTRY REVIEW(S)

CHEMISTS REVIEW	1. ORGANIZATION	2. NDA NUMBER
	DMED, HFD-510	21-301
3. NAME AND ADDRESS OF APPLICANT		4. COMMUNICATION, DATE
King Pharmaceuticals, Inc. 501 Fifth Street Bristol, TN 37620		S-028, 02-Oct-2009
5. PROPRIETARY NAME	6. NAME OF THE DRUG	7. AMENDMENTS, REPORT, DATE
Levoxyl	Levothyroxine Sodium Tablets, 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, and 200	
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 manufacturers'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 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 tablets 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	05-Oct-2009

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AP

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21301	SUPPL-28	KING PHARMACEUTICALS INC	LEVOXYL

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/s/

JANICE T BROWN
10/06/2009

ERIC P DUFFY
10/06/2009

Supplement Subtype FDA Form

NDA # 21-301

Supplement # 028

SDN 117

Supplement Subtype FDA: CBE-0

Teshara G. Bouie
Regulatory Health Project Manager
ONDQA/DPE
6-Oct-09

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/s/

TESHARA G BOUIE
10/06/2009