CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

ANDA 209713Orig1s003

Name: Levothyroxine Sodium Tablets USP, 25 mcg, 50 mcg,75 mcg, 88 mcg, 100 mcg, 112 mcg, 125 mcg, 137 mcg, 150 mcg, 175 mcg, 200 mcg, and 300 mcg

Sponsor: Lupin Pharmaceuticals, Inc.

Approval Date: June 3, 2019

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APPLICATION NUMBER:

ANDA 209713Orig1s003

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Reviews / Information Included in this Review

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Microbiology Review(s)	
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APPROVAL LETTER

ANDA 209713/S-003

CHANGES BEING EFFECTED IN 30 DAYS
APPROVAL

Lupin Pharmaceuticals, Inc.
U.S. Agent for Lupin Atlantis Holdings SA
111 South Calvert Street
Harborplace Tower, 24th Floor
Baltimore, MD 21202
Attention: Debashis Mohanty
Manager, Regulatory Affairs

Dear Debashis Mohanty:

This is in reference to your supplemental abbreviated new drug application (sANDA) received for review on January 29, 2019, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Levothyroxine Sodium Tablets USP, 25 mcg, 50 mcg, 75 mcg, 88 mcg, 100 mcg, 112 mcg, 125 mcg, 137 mcg, 150 mcg, 175 mcg, 200 mcg, and 300 mcg.

Reference is also made to any amendments submitted prior to the issuance of this letter.

The sANDA, submitted as “Changes Being Effected in 30 Days," provides for:

> Change in formulation of 50 mcg strength - for addition of colorant FD & C Blue 1 Aluminum Lake (b) (4)

We have completed the review of this sANDA, as amended, and it is approved.

REPORTING REQUIREMENTS

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98 and at section 506I of the FD&C Act. The Office of Generic Drugs should be advised of any change in the marketing status of this drug or if this drug will not be available for sale after approval. In particular, under section 506I(b) of the FD&C Act, you are required to notify the Office of Generic Drugs in writing within 180 days from the date of this letter if this drug will not be available for sale within 180 days from the date of approval. As part of such written notification, you must include (1) the identity of the drug by established name and proprietary name (if any); (2) the ANDA number; (3) the strength of the drug; (4) the date on which the drug will be available for sale, if known; and (5) the reason for not marketing the drug after approval.

ANNUAL FACILITY FEES

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions [1] with respect to self-identification of facilities and payment of annual facility fees. Your ANDA identifies at least one facility that is subject to the self-identification requirement and payment of an annual facility fee. Self-identification must occur

by June 1 of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the Federal Register notice announcing facility fee amounts. All finished dosage forms (FDFs) or active pharmaceutical ingredients (APIs) manufactured in a facility that has not met its obligations to self-identify or to pay fees when they are due will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products misbranded because of failure to self-identify or pay facility fees are subject to being denied entry into the United States.

If you have further questions regarding this supplement, you may contact Jacquelyn Truffer, Regulatory Business Process Manager, at (301) 796 - 4164.

Sincerely yours,

{See appended electronic signature page}

For:
Paul Schwartz, Ph.D.
Director, Division of Post Marketing Activities II
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

[1] Some of these provisions were amended by the Generic Drug User Fee Amendments of 2017 (GDUFA II) (Public Law 115-52, Title III).

Karen Bernard

Digitally signed by Karen Bernard
Date: 6/03/2019 09:36:19AM
GUID: 508da702000287e581cc3b10f0ce7fef

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CHEMISTRY REVIEWS

Disciplines Involved	Outcome		Disciplines Involved	Outcome
Chemistry	AC		Biopharmaceutics	NA
Microbiology	NA		Bioequivalence	NA
Facilities	AC		DMF (Chemistry)	NA
Labeling	NA		DMF (Microbiology)	NA
Submissions Assessed				
Received Date:	January 29, 2019			
Amendment(s) Received Date:	March 15, 2019			

OFFICE OF PHARMACEUTICAL QUALITY
ASSESSMENT OF SUPPLEMENT TO ABBREVIATED NEW DRUG APPLICATION

Chemistry Assessment Number :01

ANDA/Supplement Number : 209713s003

Drug Product Name, Strength : Levothyroxine Sodium Tablets USP, 25 mcg, 50 mcg, 75 mcg, 88 mcg, 100 mcg, 112 mcg, 125 mcg, 137 mcg,150 mcg, 175 mcg, 200 mcg and 300 mcg

Pharmacological Category/ Indication(s) : Treatment of Hypothyroidism

Applicant Name (or US Agent if Applicable) : Lupin Atlantis Holdings SA

Supplement Provides For : Change in formulation of 50 mcg strength - for addition of colorant FD & C Blue 1 Aluminum Lake (b) (4)

Filing Category with basis for decision/comments (based on guidance for industry/CFR quotes) : CBE30. Per SUPAC IR the proposed change is a Level 1 change (Section III.A.1) . Since this drug product is a high-risk NTI drug product, the supplement will be filed as a CBE30.

Relevant Supporting DMF(s) Cited (If Applicable)

DMF No.	DMF		Result of Assessment	Date Assessment Completed
	NA			
	Comment	(if any) on DMF Assessment, Assessor		

ASSESSMENT NOTES

The applicant proposes change in formulation in Levothyroxine Sodium Tablets USP, 50 mcg only. Specifically, to add colorant FD&C Blue 1 Aluminum Lake (b) (4) (b) (4)

(b) (4)

- The quantitative changes in composition of FD&C Blue 1 AL (b) (4) (b) (4) is tabulated below.

(b) (4)

(b) (4)

- There is no change in composition of other strengths of Levothyroxine Sodium Tablets USP i.e. 25 mcg, 75 mcg, 88 mcg, 100 mcg, 112 mcg, 125 mcg, 137 mcg,150 mcg, 175 mcg, 200 mcg and 300 mcg
- The agency may note that revised (b) (4) Structured Product Labeling (SPL) with above proposed changes shall be submitted in subsequent Annual Report after receiving the approval for the subject CBE-30 Days Supplement.

(b) (4)

Following this page, 4 Pages Withheld in Full as (b)(4)

- **RECOMMENDATION**

☒ Supplement is CMC Approvable

☐ Supplement is NOT CMC Approvable (with brief explanation:)

(Choose ☐ IR, ☐ CR-Minor, ☐ CR-Major); Deficiencies noted below:

Deficiencies to be communicated:

Primary Assessor : Yanira Gonzalez-Berrios, PhD Date : May 2, 2019

Yanira Gonzalez-Berrios

Digitally signed by Yanira Gonzalez-Berrios
Date: 5/02/2019 12:53:48PM
GUID: 534c0b6200067d385942adde56e387a5

Kathy Woodland Outlaw

Digitally signed by Kathy Woodland Outlaw
Date: 5/03/2019 08:06:44AM
GUID: 508da70000028671b774f642ccb12211

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ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

ANDA 209713/S-003

INFORMATION REQUEST

Lupin Pharmaceuticals Inc.
U.S. Agent for Lupin Atlantis Holdings SA
111 South Calvert Street
Harborplace Tower, 24th Floor
Baltimore, MD 21202
Attention: Debashis Mohanty
Manager, Regulatory Affairs

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We are reviewing the Quality section of your submission and have the following comments and information requests. We request a prompt written response, no later than March 19, 2019, in order to continue our evaluation of your sANDA.

Comments and information requests:

A. Drug Product

1. (b) (4)

Send your submission through the Electronic Submission Gateway http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm. Prominently identify the submission with the following wording in bold capital letters at the top of the first page of the submission:

INFORMATION REQUEST
QUALITY

If you do not submit a complete response by March 19, 2019, the review will be closed and the listed deficiency will be incorporated in a COMPLETE RESPONSE correspondence. For more information, please refer to the guidance for industry, *ANDA Submissions – Amendments and Easily Correctable Deficiencies Under GDUFA* available on FDA's website.

If you have any questions, please contact Jacquelyn Truffer, Regulatory Business Process Manager, at (301) 796 - 4164.

Sincerely,

{See appended electronic signature page}

Jacquelyn Truffer
Regulatory Business Process Manager
Office of Program and Regulatory Operations
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Jacquelyn Truffer

Digitally signed by Jacquelyn Truffer
Date: 3/13/2019 08:17:33AM
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