CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

ANDA 065488s001

Name: Azithromycin for Oral Suspension USP, 100 mg/5 mL and 200 mg/5 mL

Sponsor: Lupin LTD

Approval Date: May 25, 2016

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 065488s001

CONTENTS

Reviews / Information Included in this Review

Approval Letter	**X**
Other Action Letters	
Labeling	
Labeling Review(s)	
Medical Review(s)	
Chemistry Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Bioequivalence Review(s)	
Other Review(s)	**X**
Administrative & Correspondence Documents	

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 065488s001

APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

sANDA: See Attached List

APPROVAL

Lupin Pharmaceuticals, Inc.
U.S. Agent For: Lupin Limited
Attention: Sudhir Kaushal
Director, Regulatory Affairs
111 South Calvert Street, Harborplace Tower, 24th Floor
Baltimore, MD 21202

Dear Sir:

Please refer to your Supplemental Abbreviated New Drug Applications (sANDAs) dated and received May 6, 2016, submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act, regarding your abbreviated new drug applications (ANDAs) for: See Attached List.

The supplemental ANDAs, submitted as "Changes Being Effected in 30 Days," provide for:

- (b) (4)

We have completed our review of these sANDAs, and they are approved.

We remind you that you must comply with the requirements for the approved ANDA described in 21 CFR 314.80-81.

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions 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.

The material submitted is being retained in our files.

Sincerely yours,

Andrew J. Langowski -S

Digitally signed by Andrew J. Langowski -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300040726, cn=Andrew J. Langowski -S
Date: 2016.05.25 14:19:00 -04'00'

For:

Paul Schwartz, Ph.D.
Director (Acting)
Division of Post Marketing Activities II
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Group Supplement List

ANDA#	SUPP#	PRODUCT NAME	DOSAGE FORM
065398	Supplement-002	Azithromycin	Tablet
065399	Supplement-002	Azithromycin	Tablet
065400	Supplement-002	Azithromycin	Tablet
065488	Supplement-001	Azithromycin	Powder for Oral Suspension

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 065488s001

OTHER REVIEW

CBE Review Form

DISCIPLINES INVOLVED	REVIEW OUTCOME		DISCIPLINES INVOLVED	REVIEW OUTCOME
Chemistry	AC		Bio	NA
Microbiology	NA		FACILTIES	NA
Labeling	NA		DMF	Adequate
SUBMISSIONS REVIEWED				
Submission Date:	5/6/2016			
Amendment(s) Date:	NA			

Letter Date: 5/6/2016

ANDA No./Supplement No.: Group Supplement
65398/S-002
65399/S-002
65400/S-002
65488/S-001

Applicant: Lupin Ltd.

Drug Product : Azithromycin Tablets USP, 250 mg (ANDA 65398)
Azithromycin Tablets USP, 500 mg (ANDA 65399)
Azithromycin Tablets USP, 600 mg (ANDA 65400)
Azithromycin for Oral Suspension USP, 100 mg/5 mL and 200 mg/5 mL (ANDA 65488)

Supplement provide for:
Inclusion of note in drug substance, Azithromycin Monohydrate USP (DMF # 25820), test procedure for organic impurities, USP in-line with USP.

Review Notes:
Lupin added a note in Organic impurities-Procedure 2 in line with USP monograph. As per the note "Disregard peaks eluting before Azithromycin 3 '-N-oxide (Azithromycin N-oxide) and after 3-deoxyazithromycin (Azithromycin B)".

(b) (4)

Lupin provided the updated test procedure with the note in Organic impurities-Procedure 2.

(b) (4)

X Data in support of the amendments are found satisfactory:

☐ Deficiencies noted:

Recommendation:

X Supplements Approval

☐ Not approvable supplements; above deficiencies to applicant

Reviewer: Neeraj Chopra Date: 5/23/2016