CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

203195Orig1s000

MICROBIOLOGY REVIEW(S)

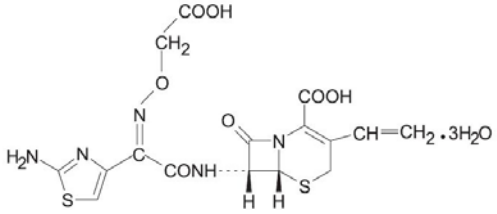
DIVISION OF ANTI-INFECTIVE PRODUCTS CLINICAL MICROBIOLOGY REVIEW

NDA: 203195 DATE REVIEW COMPLETED: 02/27/2012
505(b)(2)

Date Company Submitted: 06/28/2011
Date received by CDER: 06/28/2011
Date Assigned: 06/28/2011
Reviewer: Avery Goodwin, PhD

NAME AND ADDRESS OF APPLICANT:
LUPIN PHARMA
Harborplace Tower,
111 South Calvert Street, 21 st Floor,
Baltimore, Maryland 21202
TEL: 4105762000
FAX: 4105762221

DRUG PRODUCT NAMES:
Proprietary Name: Suprax®
Drug Name: SUPRAX® Cefixime Tablets USP
Chemical Name: (*6R,7R*)-7-[2-(2-Amino-4-thiazolyl)glyoxylamido]-8-oxo-3-vinyl-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 72-(*Z*)-[*O*-(carboxymethyl) oxime] trihydrate.
Molecular weight: 507.50 as the trihydrate.
Chemical Formula: $C_{16}H_{15}N_5O_7S_2.3H_2O$
Structural Formula:



PROPOSED DOSAGE FORM AND STRENGTH:
Suprax® is available for oral administration as 400 mg capsules

DOSAGE AND ADMINISTRATION:
Adults: The recommended dose of cefixime is 400 mg daily. This may be given as a 400 mg tablet daily or as 200 mg tablet every 12 hours. For the treatment of uncomplicated cervical/urethral gonococcal infections, a single oral dose of 400 mg is recommended.
Children: The recommended dose is 8 mg/kg/day of the suspension. This may be administered as a single daily dose or may be given in two divided doses, as 4 mg/kg every 12 hours.

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TYPE OF SUBMISSION:
NDA Labeling 505(b)(2)

PURPOSE OF SUBMISSION:
Lupin Limited herewith submitting an Original New Drug Application (NDA) for its product Suprax® Cefixime Capsules, 400 mg. Lupin is utilizing the 505(b)(2) regulatory pathway for the approval of Suprax® Cefixime Capsules, 400 mg. The reference listed drug (RLD) to support the safety and efficacy of the Lupin product is SUPRAX® Cefixime Tablets USP, 400 mg; ANDA# A065130, held by LUPIN PHARMS.

REMARKS:

MICROBIOLOGY SUBSECTION OF THE LABEL:
The microbiology section of the label was revised to reflect the current CLSI guidelines.

SUMMARY AND RECOMMENDATIONS:
From the microbiology perspective, based on analysis of the information provided by the applicant, the Reviewer recommends approval of this NDA under Section 505(b)(2) of the FD&C Act. The Agency also recommends that that Applicant update the microbiology section of the label to reflect the current CLSI guidelines.

PACKAGE INSERT:
The version of the package insert below contains only the updated microbiology section.

DIVISION OF ANTI-INFECTIVE PRODUCTS CLINICAL MICROBIOLOGY REVIEW

NDA: 203195 DATE REVIEW COMPLETED: 02/27/2012
505(b)(2)

(b) (4)

[redacted]

25 Page(s) of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page

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/s/

AVERY C GOODWIN
04/16/2012

FREDERIC J MARSIK
04/16/2012

CLINICAL Microbiology: 45-Day Meeting Checklist
505(b)(2) application
NDA 203195
Sponsor: Lupin Ltd.
Drug: SUPRAX® Cefixime Tablets USP (400mg)
Letter Date: June 28, 2011
PDUFA Goal Date: June 1, 2012

On **initial** overview of the NDA application for RTF:

No.	Item	Yes	No	Comments – See additional comments
1	Is the clinical microbiology information (preclinical/nonclinical and clinical) described in different sections of the NDA organized in a manner to allow substantive review to begin?			Not Applicable
2	Is the clinical microbiology information (preclinical/nonclinical and clinical) described in different sections of the NDA indexed, paginated, and/or linked in a manner to allow substantive review to begin?			Not Applicable
3	Is the clinical microbiology information (preclinical/nonclinical and clinical) in different sections of the NDA legible so that substantive review can begin?			Not Applicable
4	On its face, has the applicant submitted *in vitro* data in necessary quantity, using necessary clinical and non-clinical strains/ isolates, and using necessary numbers of approved current divisional standard of approvability of the submitted draft labeling?			Not Applicable
5	Has the applicant submitted draft provisional breakpoint and interpretive criteria, along with quality control (QC) parameters, if applicable, in a manner consistent with contemporary standards, which attempt to correlate criteria with clinical results of NDA studies, and in a manner to allow substantive review to begin?			Not Applicable
6	Has the applicant submitted any required animal model studies necessary for approvability of the product based on the submitted draft labeling?			Not Applicable
7	Has the applicant submitted all special/critical studies/data requested by the Division during pre-submission discussions?			Not Applicable
8	Has the applicant submitted the clinical microbiology datasets in a format which intents to correlate baseline pathogen with clinical and microbiologic outcomes exhibited by relevant pathogens isolated from test of cure or end of treatment?			Not Applicable
9	Has the applicant submitted a clinical microbiology dataset in a format which intents to determine			Not Applicable

CLINICAL Microbiology: 45-Day Meeting Checklist
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	resistance development by correlating changes in the phenotype (such as *in vitro* susceptibility) and/or genotype (such as mutations) of the baseline relevant pathogen with clinical and microbiologic outcome as exhibited by relevant pathogens isolated from test of cure or end of treatment?			
10	Has the applicant used standardized or nonstandardized methods for measuring microbiologic outcome? If nonstandardized methods were used has the applicant included full details of the method, the name of the laboratory where actual testing was done and performance characteristics of the assay in the laboratory where the actual testing was done?			Not Applicable
11	Is the clinical microbiology draft labeling consistent with 201.56 and 201.57 of the CFR, current Divisional policy.			Not Applicable
12	FROM A CLINICAL MICROBIOLOGY PERSPECTIVE, IS THIS NDA FILEABLE? **IF NO, GIVE REASONS BELOW.**	X		

Any Additional Clinical Microbiology Comments:

This is a 505(b)(2) application; the Applicant is not proposing any changes to the microbiology section of the package insert therefore items 1 through 11 are not applicable. The submission from a clinical microbiology perspective is fileable.

Avery Goodwin, Ph.D.
DAIP
Reviewing Clinical Microbiologist

Fred Marsik, Ph.D.
DAIP
Team Leader Clinical Microbiology
8 Sep 11 FIN FJM

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/s/

AVERY C GOODWIN
09/08/2011

FREDERIC J MARSIK
09/08/2011