CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

203195Orig1s000

STATISTICAL REVIEW(S)

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Translational Sciences
Office of Biostatistics

STATISTICAL REVIEW AND EVALUATION

CLINICAL STUDIES

NDA/BLA Serial Number:	203,195
Drug Name:	Suprax (cefixime 400mg capsules)
Indication(s):	Treatment of Uncomplicated UTI, Pharyngitis & Tonsillitis, Acute Bronchitis & AECB, Uncomplicated Gonorrhea (cervical/urethral)
Applicant:	Lupin Pharma
PDUFA Date:	June 1, 2012
Review Priority:	Standard
Biometrics Division:	IV
Statistical Reviewer:	Mark A. Gamalo, Ph.D.
Concurring Reviewers:	Thamban Valappil, Ph.D.
Medical Division:	Anti-infective Products
Clinical Team:	Nasim Moledina, MD
	John Alexander, MD
Project Manager:	Alison Rodgers

Keywords: Bioequivalence

1 EXECUTIVE SUMMARY

Lupin Limited, hereforth designated as Sponsor, submitted an Original New Drug Application (NDA) for its product Suprax@ Cefixime Capsules, 400 mg. The sponsor is utilizing the 505(b)(2) regulatory pathway for the approval of Suprax® Cetixime Capsules, 400 mg. The reference listed drug (RLD) to support the safety and efficacy of the Lupin product is SUPRAX® Cetixime Tablets USP, 400 mg; ANDA# A065130, held by LUPIN PHARMS.

The Sponsor has marketed Suprax since the approval of SUPRAX@ Cefixime Tablets USP, 400 mg on February 12, 2004 (ANDA# A065 130). Subsequently, it received approval for SUPRAX@ Cefixime for Oral Suspension USP, 100 mg/5 mL, (approved on February 23, 2004; ANDA# A065 129), and SUPRAX® Cefixime for Oral Suspension USP, 200 mg/5 mL (approved on April 10, 2007; ANDA# A065355).

To support the safety and efficacy of Suprax@ Cefixime Capsules, 400 mg, the sponsor conducted one (1) bioavailability/bioequivalence study to establish a clinical bridge to the RLD SUPRAX@ Cefixime Tablets USP, 400 mg (ANDA# A065 130). There are no clinical studies submitted for review. The study report submitted states that Suprax@ Cefixime Capsules, 400 mg was shown to be bioequivalent to SUPRAX@ Cefixime Tablets USP, 400 mg in healthy adults under Fasting Study (Study LBC- IO-044) conditions. We defer to the clinical pharmacology reviewer whether this conclusion is well substantiated.

The study results coupled with Public Domain Information, Suprax labeling (Lupin Pharma, 2008), and published literature constitutes currently available information for cefixime which were submitted in this NDA.

SIGNATURES/DISTRIBUTION LIST

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Date:
Statistical Team Leader: Thamban Valappil, Ph.D.

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/s/

MARK A GAMALO
02/10/2012

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02/13/2012