

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

202091Orig1s000

***Trade Name:* SUPRAX**

***Generic Name:* cefixime**

***Sponsor:* Lupin Pharma**

***Approval Date:* February 20, 2013**

***Indications:* the treatment of otitis media, acute exacerbation of chronic bronchitis, pharyngitis/tonsillitis, uncomplicated urinary tract infections, uncomplicated gonorrhea (cervical/urethral)**

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APPROVAL LETTER



NDA 202091

NDA APPROVAL

Lupin Limited c/o Lupin Pharma
Attention: Leslie Sands, US Agent
Director, Regulatory Affairs
Harborplace Tower
111 South Calvert Street, 21st Floor
Baltimore, MD 21202

Dear Ms. Sands:

Please refer to your New Drug Application (NDA) dated October 25, 2010, received October 27, 2010, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for SUPRAX (cefixime) for Oral Suspension, 500 mg/5mL.

We acknowledge receipt of your amendments dated August 17 and December 7 and 11 (2), 2012, and February 12 and 14, 2013. The August 17, 2012, submission constituted a complete response to our August 26, 2011, action letter.

This new drug application provides for a new strength, 500mg/5mL, of SUPRAX (cefixime) for Oral Suspension for the treatment of otitis media, acute exacerbation of chronic bronchitis, uncomplicated urinary tract infections, uncomplicated gonorrhea (cervical/urethral) and pharyngitis/tonsillitis.

We have completed our review of this application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the package insert). Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*, available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE-CONTAINER LABELS

Submit final printed carton and immediate-container labels that are identical to the enclosed carton and immediate-container labels submitted on February 14, 2013, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission “**Final Printed Carton and Container Labels for approved NDA 202091.**” Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

MARKET PACKAGE

Please submit one market package of the drug product when it is available to the following address:

J. Christopher Davi, MS, Sr. RPM
Food and Drug Administration
Center for Drug Evaluation and Research
White Oak Building 22, Room: 6121
10903 New Hampshire Avenue
Silver Spring, Maryland
*Use zip code **20903** if shipping via United States Postal Service (USPS).*
*Use zip code **20993** if sending via any carrier other than USPS (e.g., UPS, DHL, FedEx).*

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call J. Christopher Davi, MS, Senior Regulatory Project Manager, at (301) 796-0702.

Sincerely,

{See appended electronic signature page}

Katherine A. Laessig, MD
Deputy Director
Division of Anti-Infective products
Office of Antimicrobial products
Center for Drug Evaluation and Research

Enclosures: Content of Labeling
Carton and Container Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

KATHERINE A LAESSIG
02/20/2013