DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 202091/S-005
NDA 203195/S-006

SUPPLEMENT APPROVAL

Lupin Limited c/o Lupin Pharmaceuticals, Inc.
Attention: Mr. Sudhir Kaushal
Director, Regulatory Affairs
111 South Calvert Street
Harborplace Tower, 24th Floor
Baltimore, MD 21202

Dear Mr. Kaushal:

Please refer to your Supplemental New Drug Applications (sNDAs) dated October 4, 2016, received October 4, 2016, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Suprax (cefixime) for Oral Suspension 500 mg/5 mL [NDA 202091] and Suprax (cefixime) Capsules, 400 mg [NDA 203195].

These "Changes Being Effected" supplemental new drug applications provide for changes to the United States Package Insert (USPI) as follows:

1. Revisions to the product title and substitution of the term antibacterial drug for the term antibiotic throughout.
2. Relocation of usage information to the **INDICATIONS AND USAGE** section of the **HIGHLIGHTS OF PRESCRIBING INFORMATION** to be consistent with the location in the **FULL PRESCRIBING INFORMATION**.
3. Updates to the **(5) WARNINGS AND PRECAUTIONS section (5.6) Risk in Patients with Phenylketonuria.**
4. Revisions to (17) Patient Counseling Information.
5. Minor editorial revisions have been made throughout.

APPROVAL & LABELING

We have completed our review of these supplemental applications, as amended. They are 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), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for these NDAs, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in these supplemental applications, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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 Alison Rodgers, Regulatory Project Manager, at (301) 796-0797.

Sincerely,

{See appended electronic signature page}

Dmitri Iarikov, MD, PhD
Acting Deputy Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE(S): Content of Labeling

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

/s/

DMITRI IARIKOV
03/16/2017