DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 202091/S-004
NDA 203195/S-005

SUPPLEMENT APPROVAL

Lupin Limited c/o Lupin Pharmaceuticals, Inc.
Attention: William McIntyre, Ph.D.
Senior Vice President - Regulatory Affairs
111 South Calvert Street
Harborplace Tower, 24th Floor
Baltimore, MD 21202

Dear Dr. McIntyre:

Please refer to your Supplemental New Drug Applications (sNDA) dated December 30, 2015, received December 30, 2015, 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 "Prior Approval" supplemental new drug applications provide for revisions to the **Microbiology** subsection (12.4) and **REFERENCES** section (15) of the package insert, so as to furnish adequate information for the safe and effective use of these drugs.

APPROVAL & LABELING

We have completed our review of these supplemental applications and they are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text and with the minor editorial revisions listed below:

- In the second list of Gram-negative Bacteria, *Klebsiefla pneumoniae* corrected to *Klebsiella pneumoniae* and *Salmonelfa* species corrected to *Salmonella* species.

- *S. pneumonia* corrected to *S. pneumoniae* in Table 4.

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 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 via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications 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 this supplemental application, 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 J. Christopher Davi, MS, Senior Regulatory Project Manager, at (301) 796-0702.

Sincerely,

{See appended electronic signature page}

Sumathi Nambiar, MD, MPH
Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE: 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/

SUMATHI NAMBIAR
01/07/2016