



NDA 202091/S-007
NDA 203195/S-008

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 February 26, 2018, received February 26, 2018, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA 202091/S-007, Suprax (cefixime) Oral Suspension UPS, 500 mg/5mL
NDA 203195/S-008, Suprax (cefixime) Capsules, 400 mg

These “Changes Being Effected” supplemental new drug applications provide for updates to the labeling in accordance with the final guidance, *Systemic Antibacterial and Antifungal Drugs: Susceptibility Test Interpretive Criteria Labeling for NDAs and ANDAs*. The revisions include removal of the susceptibility test interpretive criteria from the prescribing information and replacement with text referencing the FDA Interpretive Criteria Web Page. Additionally, all references to the Clinical and Laboratory Standards Institute (CLSI) documents have been removed from the **REFERENCES** (15) section and minor editorial revisions have been made throughout the labeling.

We have completed our review of these supplemental applications. 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 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 Alison Rodgers, Regulatory Project Manager, at (301) 796-0797.

Sincerely,

{See appended electronic signature page}

Dmitri Iarikov, MD, PhD
Deputy Director (Acting)
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/

DMITRI IARIKOV
03/30/2018