

NDA 202091/S-009

SUPPLEMENT APPROVAL

Lupin Limited
c/o Lupin Pharmaceuticals, Inc.
Attention: Debashis Mohanty
Manager, Regulatory Affairs
111 South Calvert Street
Harborplace Tower, 24th Floor
Baltimore, MD 21202

Dear Mr. Mohanty:

Please refer to your supplemental new drug application (sNDA) dated April 17, 2019, received April 17, 2019, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Suprax (cefixime) for Oral Suspension, 500 mg/5 mL.

This Prior Approval supplemental application proposes changes to the prescribing information to comply with the requirements of the Pregnancy and Lactation Labeling Rule (PLLR) [79 FR 233, December 4, 2014].

Moreover, this supplemental application has been submitted in response to the December 11, 2018, Prior Approval Supplement request letter and includes revisions to the **HIGHLIGHTS OF PRESCRIBING INFORMATION, USE IN SPECIFIC POPULATIONS (8.0)** section, **Pregnancy (8.1)**, **Lactation (8.2)**, **Females and Males of Reproductive Potential Pregnancy Testing (8.3)** subsections, and the **NONCLINICAL TOXICOLOGY (13)** section, **Carcinogenesis, Mutagenesis, Impairment of Fertility (13.1)**, subsections. The **REFERENCES** section has also been updated.

APPROVAL & LABELING

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.

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 FDA.gov.¹ 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 *SPL Standard for Content of Labeling Technical Qs and As*.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, 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 Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), 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}

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

ENCLOSURE: Content of Labeling

¹ <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

DMITRI IARIKOV
10/29/2019 02:35:36 PM