



NDA 50-585/S-067

SUPPLEMENT APPROVAL

Hoffmann-La Roche, Inc.
Attention: Becky Prokipcak
OptumInsight c/o Genentech, Inc.
Regulatory Agent on behalf of Roche
1 DNA Way, MS #241B
South San Francisco, CA 94080-4990

Dear Ms. Prokipcak:

Please refer to your Supplemental New Drug Application (sNDA) dated October 7, 2014, received October 9, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Rocephin (ceftriaxone sodium) for Injection, 500 mg and 1 gm.

We also acknowledge receipt of your amendments dated March 31, April 2, and May 22, 2015, and your electronic communication of June 26, 2015.

This “Prior Approval” supplemental new drug application provides for revisions to the **CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, ADVERSE REACTIONS, (Postmarketing Experience, Cephalosporin Class Adverse Reactions), and DOSAGE AND ADMINISTRATION (NEONATES, ADULTS, COMPATIBILITY AND STABILITY)** sections of the package insert.

APPROVAL & LABELING

We have completed our review of this supplemental 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 and with the minor editorial revisions listed below and indicated in the enclosed labeling:

- **PRECAUTIONS, Influence on Diagnostic Tests:** Deletion of the [REDACTED] (b) (4)
- **DOSAGE AND ADMINISTRATION:** Specification of a dose cap in elderly patients of up to 2 grams per day, provided there is no severe renal and hepatic impairment.

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 from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes 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 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
06/30/2015