



NDA 50585/S-068

SUPPLEMENT APPROVAL

Hoffman-La-Roche, Inc.
c/o Genentech, Inc.
Attention: Patricia Smith
Regulatory Agent on behalf of Roche
1 DNA Way, MS 241B
South San Francisco, CA 94080-4990

Dear Ms. Smith:

Please refer to your Supplemental New Drug Application (sNDA) dated and received June 20, 2018, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Rocephin Kit (ceftriaxone sodium, lidocaine) for Injection.

We also refer to our letter dated May 21, 2018, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for local anesthetics. This information pertains to the risk of use of local anesthetics and the development of methemoglobinemia.

This supplemental new drug application provides for revision to the labeling for Rocephin Kit (ceftriaxone sodium, lidocaine) for Injection, based on our May 21, 2018, correspondence. The revision includes the addition of a subsection on methemoglobinemia in the **WARNINGS** section.

APPROVAL & LABELING

We have completed our review of this supplemental application. It is 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 Effectuated" (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 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 Susmita Samanta, Safety Regulatory Project Manager, at (301) 796-0803.

Sincerely,

{See appended electronic signature page}

Joseph G. Toerner, M.D., M.P.H.
Deputy Director for Safety
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. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

JOSEPH G TOERNER
07/12/2018

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