DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-585/S-058

Hoffmann-La Roche, Inc.
Attention: Lynn DeVenezia-Tobias
Program Manager
340 Kingsland Street
Nutley, NJ 07110-1199

Dear Ms. DeVenezia-Tobias,

Please refer to your supplemental new drug application dated January 15, 2007, received January 16, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Rocephin® (ceftriaxone sodium) for injection, 250 mg, 500 mg, 1g and 2g vials.

This application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

This "Changes Being Effected" supplemental new drug application provides for revisions to the **WARNINGS** section and **PRECAUTIONS/Information for Patients** subsection of the package insert in order to provide adequate information with regard to *Clostridium difficile* associated disease.

We completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text. The final printed labeling (FPL) must be identical to the enclosed package insert submitted January 15, 2007.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. For administrative purposes, designate this submission "**FPL for approved supplement NDA 50-585/S-058**." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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, Regulatory Project Manager, at (301) 796-0702.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, MD
Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Package insert submitted January 15, 2007

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Janice Soreth

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