DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-585/S-050
50-585/S-060

HLR Technology Corporation
c/o Hoffmann-La Roche, Inc.
Attention: Lynn DeVenezia Tobias
Senior Program Manager, Diversified Products
340 Kingsland Street
Nutley, NJ 07110-1199

Dear Ms. DeVenezia-Tobias:

Please refer to your supplemental new drug applications dated September 20, 2000 and August 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, 1 g and 2 g.

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

We also acknowledge receipt of your submissions dated September 24, 2002, received September 25, 2002, and April 19, 2007, received April 20, 2007, which constituted a complete response to our May 24, 2002 action letter, and your submissions of August 23, 2007, and June 18, 2008 (2), which effectively merged the amendments proposed in SLR-50 with those proposed in SLR-60.

These supplemental new drug applications provide for changes to the **PRECAUTIONS**, **ADVERSE REACTIONS**, **DOSAGE AND ADMINISTRATION, WARNINGS,** and **CONTRAINDICATIONS** sections of the package insert for Rocephin®.

We completed our review of these applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text. As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed label submitted June 18, 2008. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, designate this submissions "SPL for approved supplements NDA 50-585/S-050 and S-060."

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
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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

Sincerely,

{See appended electronic signature page}

Katherine A. Laessig, MD
Deputy Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Labeling submitted on June 18, 2008

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

/s/

Kathrine Laessig

8/18/2008 05:12:51 PM