



NDA 50-585/S-057

NDA 50-624/S-027

Hoffman-La Roche Inc.
Attention: Margaret J. Jack
Program Director
340 Kingsland Street
Nutley, NJ 07110-1199

Dear Ms. Jack:

Please refer to your new drug applications (NDAs) dated March 22, 2004, received March 24, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Rocephin[®] (ceftriaxone sodium) for injection (NDA 50-585) and Rocephin[®] (ceftriaxone injection) Galaxy[®] Container (PL2040) (NDA 50-624). These applications are subject to the exemption provisions in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

These "*Changes Being Effected*" supplements provide for revisions to the DIRECTIONS FOR USE and COMPATIBILITY AND STABILITY subsections of the DOSAGE AND ADMINISTRATION section and the HOW SUPPLIED section of the labels.

We completed our review of these applications and they are approved, effective on the date of this letter, for use as recommended in the submitted final printed labeling.

If a letter communicating important information about these new drug products (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit copies of these letters to these NDA's and copies to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

NDA 50-585/S-057
NDA 50-624/S-027
Page 2

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) 827-2125.

Sincerely,

{See appended electronic signature page}

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

Enclosures:

Attachment 1: FPL 50-585/S-057

Attachment 2: FPL 50-624/S-027

**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

9/14/04 09:37:48 AM