DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-585/S-056
NDA 50-624/S-026

Hoffman-LaRoche 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 February 6, 2004, received February 10, 2004, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Rocephin® (ceftriaxone sodium), in Galaxy containers (NDA 50-585) and in vials (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 labels to address the requirements of the Final Labeling Rule for Systemic Antibacterial Drug Products Intended for Human Use (68 FR 6062, February 6, 2003).

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 this new drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
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, 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-056
Attachment 2: FPL 50-624/S-026

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
9/2/04 04:48:29 PM