



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Silver Spring MD 20993

NDA 50-585/S-064

**SUPPLEMENT APPROVAL**

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

Dear Ms. DeVenezia-Tobias:

Please refer to your supplemental new drug application dated December 14, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Rocephin (ceftriaxone sodium) IV and IM, 500 mg and 1 g.

This "Prior Approval" supplemental new drug application provides for new safety information in the **WARNINGS** section of the label relative to reported cases of anaphylactic reactions with fatal outcome. In addition, minor revisions have been made to the **CONTRAINDICATIONS** section of the label.

We have completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed upon labeling text, which is identical to the content of labeling [21 CFR 314.50(1)(1)(i)] in structured product labeling (SPL) format submitted on December 14, 2009.

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

MedWatch  
Food and Drug Administration  
5600 Fishers Lane, Room 12B05  
Rockville, MD 20857

**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 J. Christopher Davi, MS, Senior Regulatory Project Manager at (301) 796-0702.

Sincerely,

*{See appended electronic signature page}*

Sumathi Nambiar, MD, MPH  
Deputy Director for Safety  
Division of Anti-Infective and Ophthalmology Products  
Office of Antimicrobial Products  
Center for Drug Evaluation and Research

Enclosure: Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-50585	SUPPL-64	HOFFMANN LA ROCHE INC	ROCEPHIN

---

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

---

/s/

---

JOSEPH C DAVI  
02/25/2010

SUMATHI NAMBIAR  
02/25/2010