DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21-481/S-017 **SUPPLEMENT APPROVAL**

Hoffmann-La Roche, Inc.
Attention: Barb Taylor, Ph.D.
Director, Regulatory Affairs
340 Kingsland Street
Nutley, NJ 07110-1199

Dear Dr. Taylor:

Please refer to your supplemental new drug application dated June 30, 2009, received, July 2, 2009 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Fuzeon® (enfuvirtide) for injection.

We acknowledge receipt of your submissions dated November 6, 2009, December 4, 2009, and December 17, 2009.

This Prior Approval supplemental new drug application proposes the following changes:
1. Conversion of the package insert (PI) to PLR format.
2. Add a **HOW IS FUZEON SUPPLIED?** section to the patient package insert.

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

## CONTENT OF LABELING

Within 14 days from the date of this letter, please amend all pending supplemental applications for this NDA, including pending "Changes Being Effected" (CBE) supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format that includes the changes approved in this supplemental application.

## LETTERS TO HEALTH CARE PROFESSIONALS

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 Robert G. Kosko, Jr., Pharm.D., M.P.H., Regulatory Project Manager, at (301) 796-3979 or the Division's main number at (301) 796-1500.

Sincerely,

*{See appended electronic signature page}*

Debra Birnkrant, M.D.
Director
Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure-Clean copy of approved labeling

| Application Type/Number | Submission Type/Number | Submitter Name | Product Name |
|---|---|---|---|
| NDA-21481 | SUPPL-17 | HOFFMANN LA ROCHE INC | FUZEON |

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

/s/

KENDALL A MARCUS
12/22/2009