DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-481/S-012

Hoffmann-La Roche, Inc.
Attention: Phil Johnson, Senior Program Manager
Drug Regulatory Affairs
340 Kingsland Street
Nutley, NJ 07110-119

Dear Mr. Johnson:

Please refer to your supplemental new drug application dated November 27, 2006, received November 28, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for FUZEON® (enfuvirtide) for Injection.

This supplemental application, submitted as "Supplement - Changes Being Effected" proposes to add a description of nerve bundle pain, hematoma, and cautionary wording regarding Biojector use in patients with coagulopathy to the PRECAUTIONS, ADVERSE REACTIONS, and DOSAGE AND ADMINISTRATION section of the Package Insert, as well as corresponding changes to the Patient's Package Insert. These changes were requested by FDA during a September 27, 2006 teleconference with Roche to provide additional safety information regarding the use of the Biojector 2000 to administer Fuzeon.

We completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on November 27, 2006.

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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 Elizabeth Thompson, Regulatory Project Manager, at (301) 796-0824.

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 label)

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

/s/

Debra Birnkrant
12/20/2006 03:22:38 PM
NDA 21-481