DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-481/S-007

Hoffman-La Roche, Inc.
Attention: Philip Johnson
Program Manager, Regulatory Affairs
340 Kingsland Street
Nutley, NJ 07110-1199

Dear Mr. Johnson:

Please refer to your supplemental new drug application dated January 27, 2005, received January 28, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Fuzeon® (enfuvirtide) for injection, 90 mg.

We acknowledge receipt of your submissions dated May 6, 2005 and July 26, 2005.

This supplemental new drug application provides for the following changes to the Injection Instructions portion of the labeling:

- The addition of an alternate safety syringe which has a hinged needle cover.
- Additional changes to make the instructions clearer and easier to follow.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, patient package insert, and injection instructions).

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format - NDA (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-481/S-007." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this 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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Virginia L. Behr, Chief, Project Management Staff, at (301) 827-2426.

Sincerely,

{See appended electronic signature page}

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

Enclosure:
approved draft labeling (Package Insert, Patient Package Insert, and Injection Instructions).

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

/s/

Jeffrey Murray
8/12/05 11:41:19 AM