DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-481/S-010

Hoffmann-La Roche, Inc.
Attention: Phil Johnson, Senior Program Manager
Drug Regulatory Affairs
340 Kingsland Street
Nutley, NJ 07110-1199

Dear Mr. Johnson:

Please refer to your supplemental new drug application dated September 22, 2005, received December 2, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Fuzeon® (enfuvirtide) for Injection.

We also acknowledge receipt of your amended submission dated September 28, 2006 and received September 29, 2006.

This supplemental new drug application provides revisions to the Package Insert to incorporate the safety and efficacy data from study T20-310/NV16056, "Pharmacokinetic and safety study of T-20 in combination with an optimized background in HIV infected children and adolescents." This report also includes a comprehensive data summary and discussion of ISRs in children from all studies that included pediatric patients.

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

The final printed labeling (FPL) must be identical to the enclosed labeling.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* 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. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-481/S-010**." Approval of this submission by FDA is not required before the labeling is used.

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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, M.S., 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 PI)

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
9/29/2006 10:57:37 AM
NDA 21-481