



NDA 21-481/S-006

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 26, 2005, received January 27, 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 submission dated April 27, 2005.

This "Changes Being Effected" supplemental new drug application provides for:

1. Inclusion of language regarding immune reconstitution syndrome in the Precautions section of the package insert, as requested in our letter dated April 8, 2005.
2. Addition of more descriptive information to the mixing instructions.

We completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on April 27, 2005.

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, HFD-410
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

**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
6/29/05 04:06:31 PM