



NDA 21-481/S-011

Hoffmann-La Roche, Inc.
Attention: Allison Mueller
Pharma Development Regulatory
340 Kingsland Street
Nutley, NJ 07110-119

Dear Ms. Mueller:

Please refer to your supplemental new drug application dated July 6, 2006, received July 7, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for FUZEON® (enfuvirtide) for injection.

This supplemental application proposes revisions to the Package Insert to incorporate the pharmacokinetic data from Study NP17586 entitled "Single-Dose Study of Pharmacokinetics of Enfuvirtide (FUZEON, T-20/Ro 29-9800) in HIV-1 Infected Subjects with Renal Impairment."

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 submitted labeling (package insert submitted January 5, 2007).

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-011.**" 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
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).

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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 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
1/19/2007 05:15:50 PM
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