



NDA 21-481/S-015

Hoffmann-La Roche, Inc.
Attention: Debbie Marcantuono
Sr. Program Manager, Drug Regulatory Affairs
340 Kingsland Street
Nutley, NJ 07110-1199

Dear Ms. Marcantuono:

Please refer to your supplemental new drug application dated March 13, 2008, received March 14, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Fuzeon[®] (enfuvirtide) for injection.

We also acknowledge receipt of your submission dated October 16, 2008.

This supplemental new drug application updates the CLINICAL PHARMACOLOGY, Pharmacokinetics subsection with information related to the levels of Fuzeon[®] found in cerebrospinal fluid (CSF).

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.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/oc/datacouncil/spl.html>, that is identical in content to the enclosed labeling. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "SPL for approved supplement NDA 21-481/S-015.

The final printed labeling (FPL) must be identical to the enclosed labeling (package insert and patient prescribing information).

Only use the above paragraph when there are additional labeling supplements in-house. In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

REPORTING REQUIREMENTS

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 Robert G. Kosko, Jr., Pharm.D., M.P.H., Regulatory Project Manager, at (301) 796-3979.

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 approved labeling)

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

/s/

Kendall Marcus
12/16/2008 04:46:31 PM
sign-off for Debra Birnkrant M.D.