



NDA 20-778/S-025
NDA 20-779/S-046
NDA 21-503/S-007

Pfizer Inc.
US Medical
Pfizer Global Pharmaceuticals
Attention: Ann Carey
Director U.S. Regulatory Affairs
235 East 42nd Street
New York, New York 10017-5755

Dear Ms. Carey:

Please refer to your supplemental new drug applications dated April 6, 2006, received April 7, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for VIRACEPT® (nelfinavir mesylate) 50 mg/g oral powder, VIRACEPT® (nelfinavir mesylate) 250 mg tablets and VIRACEPT® (nelfinavir mesylate) 625 mg tablets.

We acknowledge receipt of your submissions dated:

April 6, 2006	Changes Being Effected Labeling supplement - with draft study synopsis
September 13, 2006	Amendment: Final study report
December 1, 2006	Amendment: Revised labeling

These “Changes Being Effected” supplemental new drug applications provide for the addition of information from study A4301024 titled “A Study to Estimate the Effect of Omeprazole on the Pharmacokinetics of Nelfinavir in Healthy Subjects” to the CLINICAL PHARMACOLOGY – Drug Interactions section and the PRECAUTIONS-Drug Interactions section of the package insert. Additionally, these applications provide for the addition of omeprazole to the MEDICINES YOU SHOULD NOT TAKE WITH VIRACEPT section of the patient package insert.

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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 submitted labeling text with an additional minor editorial revision (listed below) – deletion of the word “omeprazole” from Table 9 (**revised text in bold font**):

Submitted labeling text:

Table 9: Drugs That Should Not be Coadministered with Viracept	
Drug Class: Drug Name	Clinical Comment
Proton Pump Inhibitors: omeprazole	Omeprazole decreases the plasma concentrations of Nelfinavir. Concomitant use of proton pump inhibitors and Viracept may lead to a loss of virologic response and development of resistance.

Approved labeling text:

Table 9: Drugs That Should Not be Coadministered with Viracept	
Drug Class: Drug Name	Clinical Comment
Proton Pump Inhibitors	Omeprazole decreases the plasma concentrations of Nelfinavir. Concomitant use of proton pump inhibitors and Viracept may lead to a loss of virologic response and development of resistance.

The final printed labeling (FPL) must be identical to the attached labeling (text for the package insert, text for the patient package insert) and include the minor editorial revision indicated. 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 these submissions "**FPL for approved supplement NDA 20-778/S-025, NDA 20-779/S-046, NDA 21-503/S-007.**" Approval of these submissions 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

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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 Anne Marie Russell, Regulatory Project Manager, at (301) 796-2014.

Sincerely,

{See appended electronic signature page}

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

Enclosure: Approved Draft Labeling (Package Insert and Patient Package Insert)

**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
12/22/2006 10:40:36 AM
NDAs 21-503, 20-779, 20-778