DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

20-778/S-023
20-779/S-044
21-503/S-003

Pfizer, Inc.
Attn: Ms. Justine King
Regulatory Manager
150 E. 42nd St.
New York, NY 10017-5755

Dear Ms. King:

Please refer to your supplemental new drug applications dated December 3, 2003, received December 4, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Viracept® (nelfinavir mesylate) 250 mg tablets, Viracept® (nelfinavir mesylate) oral powder, and Viracept® (nelfinavir mesylate) 625 mg tablets.

These supplemental new drug applications provide for labeling changes to the Pharmacokinetics subsection of the CLINICAL PHARMACOLOGY section, and to the Carcinogenisis, Mutagenisis and Impairment of Fertility subsection of the PRECAUTIONS section.

We completed our review of these supplemental new drug applications. They are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text submitted on May 28, 2004 (Package insert, Patient Package insert.)

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, please call Destry Sillivan, Regulatory Project Manager, at (301) 827-2335.

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/

Debra Birnkrant
6/4/04 12:34:05 PM
NDA 21-503, 20-779, 20-778