DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-779/SE5-042 (250 mg tablets)
NDA 20-778/SE5-022 (oral powder)
NDA 21-503/SE5-001 (625 mg tablets)

Pfizer Inc.
Attn: Phyllis M. Christesen, Senior Director/Team Leader
US Regulatory Affairs
235 East 42nd Street
New York, NY 10017-5755

Dear Ms. Christesen:

Please refer to your supplemental new drug applications dated June 19, 2003, received June 20, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Viracept® (nelfinavir mesylate) 250 mg tablets, oral powder, and 625 mg tablets.

We acknowledge receipt of your submissions dated:

August 1, 2003	October 30, 2003	March 10, 2004
August 21, 2003	November 5, 2003	March 12, 2004
September 2, 2003	December 19, 2003	March 16, 2004
September 25, 2003	February 16, 2004	
October 22, 2003	February 20, 2004	
October 23, 2003	March 5, 2004	

In addition we acknowledge your submissions emailed to us on March 16, and 17, and 18, 2004.

These supplemental new drug applications provide for the use of Viracept® (nelfinavir mesylate) 250 mg tablets and oral powder in combination with other antiretroviral agents for the treatment of HIV-1 infection in pediatric patients from two to thirteen years of age.

We completed our review of these applications, as amended. These applications are 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 enclosed labeling (text for the package insert and text for the patient package insert, dated March 18, 2004).

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission

should be designated **"FPL for approved supplement NDA 20-779/S-042, NDA 20-778/S-022, 21-503/S-001".** Approval of these submissions by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have fulfilled the pediatric study requirement for this application.

In addition, submit three copies of the introductory promotional materials that you propose to use for these products. 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:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Jeff O'Neill, 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

Enclosure Approved Draft Labeling (product 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
3/19/04 02:22:45 PM
NDA 20-779, 21-503, 20-778