Pfizer Inc
235 East 42nd Street
New York, NY 10017-5755

May 6, 2008

VIRACEPT® (nelfinavir mesylate) 250 mg, 625 mg tablets, and Powder for Oral Suspension
IMPORTANT INFORMATION FOR PRESCRIBERS

Dear Healthcare Professional:

The purpose of this letter is to inform you that Pfizer and FDA have agreed on a final limit for ethyl methane sulfonate (EMS) in nelfinavir mesylate (active ingredient in Viracept®) and to provide guidance on the use of Viracept in patients.

On September 10, 2007, Pfizer informed prescribers of the presence of EMS, a process-related impurity in nelfinavir mesylate (active ingredient in Viracept) and provided guidance on the use of VIRACEPT® in pregnant female and pediatric patients. At that time, FDA asked Pfizer to implement an interim specification to limit the presence of EMS in nelfinavir mesylate used in Pfizer's Viracept products marketed in the United States, while continuing to work towards a long-term specification. Healthcare providers were advised not to initiate antiretroviral regimens containing VIRACEPT® in their pregnant female and pediatric patients. In addition, pregnant females who were receiving Viracept® were to be switched to alternative anti-retroviral therapy unless no alternative therapy was available to them. For pediatric patients who were stable on Viracept-containing regimens, the FDA and Pfizer agreed that the benefit-risk ratio remained favorable and those patients could continue to receive Viracept. There was no change in the recommended use of Viracept for all other patients.

Effective March 31, 2008, all Viracept® manufactured and released by Pfizer meets the new final limits established by the FDA for prescribing to all patient populations, including pregnant female and pediatric patients.

Please see enclosed full prescribing information.

Sincerely,

William A. Erhardt, M.D.
Vice President Specialty Medical

Safety Information

VIRACEPT® in combination with other antiretroviral agents is indicated for the treatment of HIV infection.

Nelfinavir is principally metabolized by the liver; it can be used in patients with mild hepatic impairment without any dose adjustment. VIRACEPT should not be use in patients with either moderate or severe hepatic impairment.

Exercise caution when administering VIRACEPT with drugs that induce CYP3A, and with potentially toxic drugs that are metabolized by CYP3A, including those that prolong the QT interval.

In clinical studies (n>5000), the most common adverse event, diarrhea, was moderate to severe in 14% to 20% of patients.

Immune reconstitution syndrome has been reported in patients treated with combination antiretroviral therapy, including VIRACEPT.

Redistribution/accumulation of body fat has been reported in patients receiving antiretroviral therapy. A causal relationship has not been established, and long-term consequences are not known at this time.

New onset diabetes mellitus, exacerbation of pre-existing diabetes mellitus and hyperglycemia have been reported with protease inhibitors.

There are no adequate and well-controlled studies in pregnant women taking VIRACEPT. VIRACEPT should be used in pregnancy only if clearly needed.

VIRACEPT use is contraindicated with amiodarone, quinidine, triazolam, midazolam, ergot derivatives, and pimozide. VIRACEPT should not be coadministered with St. John's wort, simvastatin, lovastatin, rifampin, and omeprazole. Rifabutin dose should be reduced by 50%. PDE5 inhibitors should be prescribed with caution.

Increased bleeding in patients with hemophilia type A or B has been reported with protease inhibitors.