DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-938/S-006
NDA 21-938/S-007
NDA 21-938/S-008

Pfizer Inc.
Attention: Laurie Strawn, Ph.D.
10646 Science Center Drive
San Diego, CA 92121

Dear Dr. Strawn:

Please refer to your supplemental new drug applications dated October 2, 2007, March 25, 2008, and March 27, 2008, submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for SUTENT, capsules 12.5 mg, 25 mg, 50 mg Sunitinib equivalent.

We acknowledge receipt of your submissions dated October 2, 2007, March 25, 2008, March 27, 2008, August 20, 2008, and September 30, 2008

SLR-006 "Changes Being Effected" supplemental new drug application provides for addition of information to Section 6, Adverse Reactions on serious infection and myopathy/rhabdomyolysis.

SLR-007 "Changes Being Effected" supplemental new drug application provides for additional information to Section 6, Adverse Reactions of thrombotic microangiopathy and proteinuria/nephrotic syndrome.

SLR-008 "Prior Approval Supplement" supplemental new drug applications provide for revisions to Section 5, Warning and Precautions to add information on hyperthyroidism.

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.

As soon as possible, but no later than 14 days from the date of this letter, please submit the 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 to the September 30, 2008 labeling text. 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 NDA 21-938/S-006, S-007, and S-008."

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
Suite 12B05
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 Milinda Vialpando, Regulatory Project Manager, at (301) 796-1444.

Sincerely,

{See appended electronic signature page}

Robert Justice, M.D.
Director
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure

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

/s/

Robert Justice

11/7/2008 06:45:18 PM