



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 21-938/S-009

Pfizer Inc.  
Attention: Ann Carey  
Director Regulatory Affairs  
235 East 42<sup>nd</sup> Street  
New York, NY 10017-5755

Dear Ms. Carey:

Please refer to your supplemental new drug application dated May 21, 2008, received May 21, 2008, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Sutent, Capsules 12.5 mg, 25 mg, 50 mg Sunitinib equivalent.

This supplemental new drug application provides for a revision to the drug product manufacturing process and the addition of a new dosage strength, 37.5 mg capsules.

We completed our review of this application. This application is 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 submitted labeling (package insert submitted May 21, 2008). 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."

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

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Robert Justice  
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