DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-923/S-003

Bayer Pharmaceuticals Corporation
Attention: Robert E. Kessler, Ph.D.
Deputy Director, Global Regulatory Affairs, Therapeutics Area Oncology
400 Morgan Lane
West Haven, CT 06516

Dear Dr. Kessler:

Please refer to your supplemental new drug application dated September 5, 2006, received September 6, 2006, submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Nexavar® (sorafenib tosylate) Tablets 200mg.

This "Changes Being Effected" supplemental new drug application provides for revisions to the package insert PRECAUTIONS and ADVERSE EVENTS sections, and the patient package insert "What are possible side effects of Nexavar" section.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the labeling submitted September 5, 2006 (package insert and 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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Patricia Garvey, Senior Regulatory Project Manager, at (301) 796-1356.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D.
Director
Division of Drug Oncology Products
Office of Oncology Drug Products
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/

Robert Justice

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