DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-588/S-007

Novartis Pharmaceuticals Corporation
One Health Plaza
Hanover, New Jersey 07936-1080

Attention: Robert Miranda, Director
Drug Regulatory Affairs

Dear Mr. Miranda:

Please refer to your supplemental new drug application dated December 16, 2004, received December 17, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Gleevec® (imatinib mesylate) Tablets, 100 and 400 mg.

This "Changes Being Effected" supplemental new drug application provides for labeling changes to the package insert to include information from a two-year carcinogenicity study in rats.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on December 16, 2004.

However, we remind you of your agreement to replace the sentence "The no-effect levels (NOELs) for the various target organs with neoplastic lesions were 15 mg/kg/day for the preputial and clitoral gland and 30 mg/kg/day for the kidney and urinary bladder." with "No tumors in the urogenital tract were observed at 15 mg/kg/day." at the next printing and that further labeling changes may be warranted upon the Agency's review when the final study report is submitted.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. 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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Ann Staten, Regulatory Project Manager, at (301) 594-0490.

Sincerely,

{See appended electronic signature page}

Richard Pazdur, M.D.
Director
Division of Oncology Drug Products
Office of Drug Evaluation I
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/

Richard Pazdur

5/18/05 11:56:02 AM