



NDA 21-588/S-008, S-010

Novartis Pharmaceuticals Corporation
One Health Plaza, Bldg. 105/Rm 2W200
East Hanover, NJ 07936-1080

Attention: Joseph Quintavalla
Senior Regulatory Manager
Drug Regulatory Affairs

Dear Mr. Quintavalla:

Please refer to your supplemental new drug application dated December 7, 2005 (S-008/S-010), received December 8, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Gleevec® (imatinib mesylate).

We also refer to your submission dated December 13, 2005 (S-008/S-010).

We note that the labeling dated December 13, 2005 provides for a combination of the final printed labeling for S-008 approved on October 20, 2005 and the final printed labeling (FPL) for the new "Changes Being Effectuated" supplement S-010.

We have reviewed the labeling for S-008 that you submitted in accordance with our October 20, 2005 letter and we find it acceptable.

This "Changes Being Effectuated" supplemental new drug application (S-010) provides for adding new precautionary and adverse reaction information to the package insert.

We have completed our review of this supplemental new drug application (S-010). It is approved, effective on the date of this letter, for use as recommended in the final printed labeling submitted on December 13, 2005.

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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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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) 796-1468.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D.
Acting 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
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/s/

Robert Justice
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