DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-588/S-025

Novartis Pharmaceutical Corporation
Attention: Robert A. Miranda
Executive Director, Drug Regulatory Affairs
One Health Plaza
East Hanover, NJ 07936-1080

Dear Mr. Miranda:

Please refer to your supplemental new drug application dated June 24, 2008, received June 24, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Gleevec® (imatinib mesylate) Tablets, 100 mg and 400 mg.

We acknowledge receipt of your submission dated August 21, December 17, and December 18, 2008.

This new drug application provides for the use of Gleevec® (imatinib mesylate) Tablets, 100 mg and 400 mg, for the adjuvant treatment of adult patients following complete gross resection of Kit (CD117) positive gastrointestinal stromal tumors (GIST).

We have completed the review of this supplemental application, as amended. It is approved under the provisions of the accelerated approval regulations (21 CFR 314.510), effective on the date of this letter, for use as recommended in the enclosed labeling text. Marketing of this drug product and related activities must adhere to the substance and procedures of the referenced accelerated approval regulations.

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

PEDIATRIC RESEARCH EQUITY ACT

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because this drug product for this indication has an orphan drug designation, you are exempt from this requirement.

ACCELERATED APPROVAL

Products approved under the accelerated approval regulations, 21 CFR 314.510, require further adequate and well-controlled trials to verify and describe clinical benefit. We remind you of your post marketing requirements (Subpart H Phase 4 requirements) specified in your submission (e-mail) dated December 18, 2008 that are listed below.

1. To complete the ongoing clinical trial entitled "A single phase III randomized double-blind study of adjuvant imatinib versus placebo in patients who had complete gross resection of their primary gastrointestinal stromal tumor (GIST)" and provide a report and datasets at four years of follow-up for relapse-free survival.

Protocol Submission:	NA
Trial Start Date:	July 31, 2002 (in progress)
Study Report Submission:	November 30, 2010

2. To complete the ongoing clinical trial entitled "A single phase III randomized double-blind study of adjuvant imatinib versus placebo in patients who had complete gross resection of their primary gastrointestinal stromal tumor (GIST)" and provide a report and datasets at five years of follow-up for relapse-free survival.

Protocol Submission:	NA
Trial Start Date:	July 31, 2002 (in progress)
Report and Dataset Submission:	November 30, 2011

3. To complete the ongoing clinical trial entitled "A single phase III randomized double-blind study of adjuvant imatinib versus placebo in patients who had complete gross resection of their primary gastrointestinal stromal tumor (GIST)" and provide a report and datasets after collection of 5 years of overall survival data.

Protocol Submission:	NA
Trial Start Date:	July 31, 2002 (in progress)
Report and Dataset Submission:	November 30, 2011

4. To complete the clinical trial entitled "Short (12 months) versus long (36 months) duration of adjuvant treatment with the tyrosine kinase inhibitor imatinib mesylate of operable GIST with a high risk of recurrence (SSG XVIII/AIO)" and provide a report and datasets.

Protocol Submission:	NA
Trial Start Date:	February 2004 (in progress)
Report and Dataset Submission:	November 30, 2011

Final reports should be submitted to this NDA as supplemental applications. For administrative purposes, all submissions relating to these Phase 4 requirements must be clearly designated "**Subpart H Phase 4 Requirements**."

CONTENT OF LABELING

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 enclosed labeling (text for the package insert). 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 21-588/S-025."

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

PROMOTIONAL MATERIALS

Immediately submit all promotional materials (both promotional labeling and advertisements) to be used within the first 120 days after approval. Send one copy to the Division of Drug Oncology Products and two copies of the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

We also remind you that, under 21 CFR 314.550, after the initial 120 day period following this approval, you must submit all promotional materials, including promotional labeling as well as advertisements, at least 30 days prior to the intended time of initial dissemination of the labeling or initial publication of the advertisement.

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 Susan Jenney, Regulatory Project Manager, at (301) 796-0062.

Sincerely,

{See appended electronic signature page}

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

Enclosure (Package Insert)

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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