DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-588/SE7-024

Novartis Pharmaceutical Corporation
Attention: Robert A. Miranda
One Health Plaza
East Hanover, NJ 07936-1080

Dear Mr. Miranda:

Please refer to your supplemental new drug application dated November 29, 2007, received November 29, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Gleevec® (imatinib mesylate) Tablets.

We acknowledge receipt of your submission dated February 1, 2008 and emails dated September 22, and 24, 2008.

This supplemental new drug application provides for the use of Gleevec (imatinib mesylate) Tablets for patients with Kit (CD117) positive unresectable and/or metastatic malignant gastrointestinal stromal tumors (confirmatory studies).

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 agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the September 24, 2008 submission by email, enclosed labeling (text for package insert).

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 September 24, 2008 submitted labeling (text for package insert, text for the patient 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/SE7-024."

We approved this NDA for several indications under the regulations at 21 CFR 314 Subpart H for accelerated approval of new drugs for serious or life-threatening illnesses. Approval of this supplement fulfills your commitment, Post-marketing Commitment #3 in our February 1, 2002 Approval letter made under 21 CFR 314.510 for this indication (GIST).

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and

effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

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:

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

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

Sincerely,

{See appended electronic signature page}

Ann T. Farrell, M.D.
Deputy Director
Division of Drug Oncology Drug 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 this page is the manifestation of the electronic signature.

/s/

Ann Farrell

9/26/2008 10:50:28 AM