



NDA 21-588/S-023

Novartis Pharmaceuticals Corporation
Attention: Maged Darwish
Associate Director, Global Regulatory CMC
One Health Plaza
East Hanover, NJ 07936-1080

Dear Mr. Darwish:

Please refer to your supplemental new drug application dated November 20, 2007, received November 20, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Gleevec® (imatinib mesylate) Tablets, 100mg.

This “Changes Being Effectuated in 30 days” supplemental new drug application provides for a change in the number of tablets from 100 to 90 tablets per bottle of Gleevec® Tablets, 100 mg.

Please correct the Product Information section in the final SPL/FPL, to include the updated number of tablets in the bottle and the updated NDC number.

We completed our review of this application. 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 enclosed labeling (text for the package insert, immediate container labels).

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-023.”

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

Sincerely,

{See appended electronic signature page}

Hasmukh B. Patel, Ph.D.
Branch Chief
Branch 8, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
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/

Hasmukh Patel

4/30/2008 11:11:22 AM