



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-588/SLR-022

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 13, 2007, received November 13, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Gleevec® (imatinib mesylate) Tablets.

This supplemental new drug application provides for revising the labeling to add information about increased hepatotoxicity and hypothyroidism.

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 for S-024.

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 (test for package insert, test 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/SE7-022."

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

**This is a representation of an electronic record that was signed electronically and
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/s/

Ann Farrell
9/26/2008 08:55:09 AM