



NDA 21-588/S-026 and S-028

Novartis Pharmaceuticals Corporation  
Attention: Shanthi Ganeshan, Ph.D.  
Director, Drug Regulatory Affairs, Oncology Global Development  
One Health Plaza  
East Hanover, NJ 07936-1080

Dear Dr. Ganeshan:

Please refer to your supplemental new drug applications dated August 1, 2008 and March 16, 2009, received August 1, 2008, and March 16, 2009, respectively, 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 submissions dated February 16, March 18, and May 26, 2009.

S-026 supplemental new drug application provides for the use of Gleevec (imatinib mesylate) Tablets, 100 mg and 400 mg for the treatment of newly diagnosed adult patients with Philadelphia chromosome positive chronic myeloid leukemia (CML) in the chronic phase. The supplement updated the label with long term data from study 0106 and fulfills the final subpart H postmarketing commitment for CML.

S-028 supplemental new drug application provides for updating the "Nursing Mothers" subsection of the USE IN SPECIFIC POPULATIONS section and the OVERDOSAGE section of the package insert to include new safety updates from the postmarketing reports and new safety information.

We have completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text submitted on May 26, 2009.

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-026, S-028."

We approved this NDA 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 commitments made under 21 CFR 314.510.

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) 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

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see [www.fda.gov/cder/ddmac](http://www.fda.gov/cder/ddmac).

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}*

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

Enclosure (package insert)

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

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Robert Justice  
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