NDA 021588/S-063

SUPPLEMENT APPROVAL

Novartis Pharmaceuticals Corporation
Attention: Maria Santos
RA CMC Associate Director
One Health Plaza
East Hanover, NJ 07936

Dear Maria Santos:

Please refer to your Supplemental New Drug Application (sNDA) dated November 2, 2023, received November 2, 2023, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Gleevec (imatinib mesylate) tablets.

We also refer to our approval letter dated March 1, 2024, which did not contain the following: Updated USPI

This replacement approval letter incorporates the correction of the error. The effective approval date will remain March 1, 2024, the date of the original approval letter.

This Prior Approval supplemental new drug application provides for:

1) Addition of Novartis d.o.o., Ljubljana, Slovenia (FEI # 3013358387) as an alternate site for the drug product manufacture, quality control and stability testing, primary and secondary packaging, storage and quarantine, and related changes.
2) Addition of (b) (4) as an alternative drug product quality control and stability testing site.
3) Addition of Novartis d.o.o., Ljubljana, Slovenia, (b) (4) as storage and quarantine sites.
4) Deletion of Novartis Pharma Stein AG, Stein, Switzerland registered. as a drug product manufacturing site that is no longer in use.
5) Change in the name of site responsible for manufacturing, quality control of the drug substance and site responsible for quality control of the drug product.
6) Addition of the new presentation for Gleevec 400 mg tablets blister pack.
7) United States Prescribing Information (USPI) with new NDC for additional presentation for the Gleevec 400 mg tablets blister pack.

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the prescribing information) with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

Also, within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

CARTON AND CONTAINER LABELS

Submit final printed carton and container labels that are identical to carton and container labels submitted on February 28, 2024, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications. For administrative purposes, designate this submission **"Product Correspondence – Final Printed Carton and Container Labels for approved NDA 021588/S-063."** Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Dahlia A. Walters, Regulatory Business Process Manager, at (301) 796 - 8427.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, Ph.D.
Supervisor
Division of Product Quality Assessment IV
Office of Product Quality Assessment I
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):
Carton and Container Labeling
Content of Labeling

Ramesh Raghavachari

Digitally signed by Ramesh Raghavachari
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