DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 206910/S-010
NDA 207968/S-005

SUPPLEMENT APPROVAL

Novartis Pharmaceuticals Corporation
Attention: Nupur Mittal, PharmD
Sr. Global Program Regulatory Manager
Regulatory Affairs, Oncology
One Health Plaza
East Hanover, NJ 07936-1080

Dear Dr. Mittal:

Please refer to your Supplemental New Drug Application (sNDA) dated July 26, 2018, received July 26, 2018, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Jadenu® (deferasirox) Tablets, 90 mg, 180 mg, 360 mg.

We also refer to your Supplemental New Drug Application (sNDA) dated July 26, 2018, received July 26, 2018, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Jadenu® Sprinkle (deferasirox) Granules, 90 mg, 180 mg, 360 mg.

These "Changes Being Effected" supplemental new drug applications provide for revisions to the prescribing information for Jadenu and Jadenu Sprinkle **WARNINGS AND PRECAUTIONS**, **ADVERSE REACTIONS** and **USE IN SPECIFIC POPULATIONS** sections in response to the Agency June 14, 2018 Supplement Request letter.

APPROVAL & LABELING

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text and with the minor editorial revision listed below.

In the **HIGHLIGHTS** section, revise the date from "Revised: 7/2018" to "Revised: 8/2018".

WAIVER OF HIGHLIGHTS SECTION

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information.

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, except with the revision listed, 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 submitted 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 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 with the revisions listed above 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).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your applications, you are exempt from this requirement.

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the address above, by fax to 301-847-8444, or electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft guidance for industry (available at:

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf).

REPORTING REQUIREMENTS

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 Diane Leaman, Safety Regulatory Project Manager, at (301) 796 1424.

Sincerely,

{See appended electronic signature page}

Barry W. Miller
Deputy Director for Safety, Acting
Division of Hematology Products
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

BARRY W MILLER
08/03/2018