NDA 021877/S-012

SUPPLEMENT APPROVAL

Novartis Pharmaceuticals Corporation
Attention: Lu Wu
Global Program Regulatory Manager, Regulatory Affairs
One Health Plaza
East Hanover, NJ 07936

Dear Mr. Wu:

Please refer to your Supplemental New Drug Application (sNDA) dated and received April 3, 2019, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Arranon (nelarabine) Injection, 250 mg/50 mL.

We also refer to our approval letter dated August 2, 2019, which contained the following error: "The Prescribing Information changes from Supplement 10, an Efficacy Supplement, approved on July 31, 2019 were not incorporated into the attached labeling." This replacement approval letter incorporates the correction of the error. The effective approval date will remain August 2, 2019, the date of the original approval letter.

This Prior Approval supplemental new drug application provides for:

- Addition of an alternative drug product manufacturing and packaging site, (b) (4)
- Addition of alternative drug product quality control sites, including (b) (4) (b) (4)
- Addition of a package of 1 x 50 mL single dose vial presentation for the finished product at (b) (4) site.
- Additional changes associated with the transfer of manufacturing and quality control testing to the proposed sites.

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 text.

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 IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to enclosed carton and immediate container labels, 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 – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3)*. For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 021877/S-012.**" 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 Chelsea Bostic, Regulatory Business Process Manager, at (301) 796 - 8862.

Sincerely,

{See appended electronic signature page}

For
Ramesh Raghavachari, Ph.D.
Chief, Branch I
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):
Content of Labeling

David Lewis

Digitally signed by David Lewis
Date: 12/15/2022 08:05:02AM
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