NDA 205582/S-12

SUPPLEMENT APPROVAL

Sun Pharma Global FZE
Attention: Ronak Patel
U.S. Agent
2 Independence Way
Sun Pharmaceutical Industries, Inc.
Princeton, NJ 08540

Dear Mr. Patel:

Please refer to your supplemental new drug application (sNDA) dated January 18, 2020, received January 21, 2020, and your amendment dated January 30, 2020, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Decitabine injection.

This Prior Approval supplemental new drug application provides for the addition of Differentiation syndrome and minor editorial revisions to Sweet's syndrome to the Adverse Reactions subsection 6.2 Postmarketing Experience.

APPROVAL & LABELING

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

- Highlights of Prescribing Information updated to reflect "Revised: 02/2020".
- Last page of label revised to include the date of last revision as "ISS. 02/2020" 2020".

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 FDA.gov.[1] 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.

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

Information on submitting SPL files using eList may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.[2]

The SPL will be accessible from 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 Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), 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 application, you are exempt from this requirement.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

If you have any questions, you may contact me at (240) 402-4932 or via email at Felicia.diggs@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Shanthi Marur, M.B.B.S., M.D.
Associate Director for Safety (acting)
Office of Oncologic Diseases
Center for Drug Evaluation and Research

ENCLOSURE:

- Content of Labeling
    - Prescribing Information

U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.gov

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