



NDA 208313

NDA APPROVAL

Sun Pharmaceutical Industries Limited
Attention: Karin A. Kook, Ph.D.
U.S. Agent for Sun Pharmaceutical Industries Limited
Salamandra, LLC
One Bethesda Center
4800 Hampden Lane, Suite 900
Bethesda, Maryland 20814-2998

Dear Dr. Kook:

Please refer to your New Drug Application (NDA) dated, March 29, 2015, received on March 30, 2015, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA), for Infugem (gemcitabine in 0.9% sodium chloride injection), 10 mg/mL, for intravenous use.

We also refer to our approval letter and attached labeling dated July 16, 2018. Upon further review of the approved labeling an error was identified in the Clinical Studies Sub-Section 14.1, entitled "Ovarian Cancer" in the U.S. Prescribing Information (USPI). Specifically, the following paragraph was inadvertently omitted:

"Baseline demographics and disease characteristics in gemcitabine plus carboplatin arm were: median age of 59 (range: 36 to 78), 94% ECOG PS 0-1. 8% had evaluable disease and 92% had bidimensionally measurable disease. 40% had 6 to 12 months of platinum free interval, 59% had greater than 12 months platinum free interval; and as first-line therapy, 70% had platinum-taxane combination, 29% had platinum-non-taxane combination and 1% had platinum monotherapy."

This replacement approval letter and attached labeling incorporates the correction of this error by placing this paragraph in the attached labeling. The effective approval date will remain July 16, 2018, the date of the original approval letter.

We acknowledge your amendment (Class 2 Resubmission) submitted and received on February 16, 2018, which constituted a complete response to our May 23, 2017, Complete Response letter. We also acknowledge your amendment (Class 2 Resubmission) submitted and received November 23, 2016, which constituted a complete response to our November 24, 2015, Complete Response letter.

This new drug application provides for the use of Infugem (gemcitabine in 0.9% sodium chloride injection), 10 mg/mL, for intravenous use for the following indications:

- in combination with carboplatin, for the treatment of advanced ovarian cancer that has relapsed at least 6 months after completion of platinum-based therapy,
- in combination with paclitaxel, for first-line treatment of metastatic breast cancer after failure of prior anthracycline-containing adjuvant chemotherapy, unless anthracyclines were clinically contraindicated,
- in combination with cisplatin for the treatment of non-small cell lung cancer; and
- as a single agent for the treatment of pancreatic cancer.

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 text.

WAIVER OF HIGHLIGHTS SECTION

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

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, Instructions for Use). 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*, available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton, immediate container, and overwrap labels that are identical to the carton, immediate container, and overwrap labels submitted on June 18, 2018, 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 titled *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3)*. For administrative purposes, designate this submission “**Final Printed Carton, Container, and Overwrap Labels**”

for approved NDA 208313. Approval of this submission by FDA is not required before the labeling is used.

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.

We are waiving the pediatric studies requirement for this application because necessary studies are impossible or highly impracticable for this pediatric population.

PROMOTIONAL MATERIALS

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 prescribing information, Medication Guide, and patient PI (as applicable) to:

OPDP Regulatory Project Manager
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705-1266

Alternatively, you may submit a request for advisory comments 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>).

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the prescribing information, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>. Information and Instructions for completing the form can be found at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

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 Nataliya Fesenko, Pharm.D., Regulatory Health Project Manager, at (240) 402-6376.

Sincerely,

{See appended electronic signature page}

Joseph Gootenberg, M.D.
Deputy Director
Division of Oncology Products 2
Office of Hematology and Oncology
Center for Drug Evaluation and Research

Enclosures:

Content of Labeling
Instructions for Use
Carton, Immediate Container, and Overwrap 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/

JOSEPH E GOOTENBERG
07/16/2018