NDA 020571/S-053

SUPPLEMENT APPROVAL

Pfizer Inc.
Attention: Niki Elphick
Director, Pfizer Global Regulatory Affairs
Route 206 North
Peapack, NY 07977

Dear Ms. Elphick:

Please refer to your supplemental new drug application (sNDA) received July 30, 2021, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Camptosar (irinotecan hydrochloride).

This Prior Approval sNDA provides for revisions to the Prescribing Information (PI), Section 2 Dosage and Administration, Subsection 2.3 Dosage in Patients With Reduced UGT1A1 Activity, Section 5 Warning and Precautions, Subsection 5.3 Patients With Reduced UGT1A1 Activity, and Section 12 Clinical Pharmacology, Subsections 12.3 Pharmacokinetics to reflect that UGT1A1*6 and *28 alleles have shown to be associated with an increased risk of neutropenia and newly added 12.5 Pharmacogenomics to reflect that UGT1A1*6 and *28 alleles have shown to be associated with an increased risk of neutropenia and diarrhea.

Additional revisions were made to the PI Section 2 Dosage and Administration, Subsections 2.5 Preparation of Infusion Solution, and 2.6 Safe Handling, Section 3 Dosage Forms and Strengths and Section 16 How Supplied/Storage and Handling and other minor editorial changes.

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.

WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

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 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.

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).

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[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[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, call Autumn Zack-Taylor, M.S., Regulatory Health Project Manager, at (240) 402-5913.

Sincerely,

{See appended electronic signature page}

'Lola Fashoyin-Aje, M.D., M.P.H.
Deputy Director
Division of Oncology 3
Office of Oncologic Diseases
Center for Drug Evaluation and Research

ENCLOSURE:

- Content of Labeling
  - Prescribing Information

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/

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