NDA 217899/S-002

SUPPLEMENT APPROVAL

Gilead Sciences, Inc.
Attention: Priyanka Kothari
Associate Director, Regulatory Affairs
333 Lakeside Drive
Foster City, CA 94404

Dear Priyanka Kothari:

Please refer to your supplemental new drug application (sNDA) dated and received June 27, 2025, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Livdelzi (seladelpar) capsules.

This Prior Approval sNDA provides for changes to the following:

- DRUG INTERACTIONS, Effect of Other Drugs on Livdelzi subsection to add guidance on concomitant drug use based on three in vitro drug-drug interaction studies, one physiologically-based pharmacokinetic (PBPK) study, and one population pharmacokinetic (PopPK) study.

- CLINICAL PHARMACOLOGY, Pharmacokinetics subsection to update seladelpar exposure information in patients with primary biliary cholangitis (PBC) and severe hepatic impairment (Child-Pugh C) based on pharmacokinetic, pharmacogenomics, and safety data from the final analysis of phase 1b Study CB8025-21838, titled *An Open-Label, Non-Randomized, Single Dose Study to Evaluate the Pharmacokinetic Profile, Pharmacodynamic Effect, and Safety of Seladelpar in Adult Patients with Hepatic Impairment and Primary Biliary Cholangitis (PBC) or Primary Sclerosing Cholangitis (PSC).*

- CLINICAL STUDIES, HOW SUPPLIED/STORAGE AND HANDLING sections and Patient Package Insert to include minor format and content 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.

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, and Patient Package Insert), 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).

PATENT LISTING REQUIREMENTS

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

REPORTING REQUIREMENTS

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

[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, contact Kirti Patel, Senior Regulatory Project Manager, at Kirti.Patel@fda.hhs.gov or (301) 796-1082.

Sincerely,

{See appended electronic signature page}

Katherine S. Won PharmD, MBA, BCSCP, RAC
CDR, U.S. Public Health Service
Acting, Deputy Director for Safety
Division of Hepatology and Nutrition
Office of Immunology and Inflammation
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert

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/

KATHERINE S WON
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