NDA 208794/S-001

SUPPLEMENT APPROVAL

TerSera Therapeutics LLC
Attention: Jay Ford
Vice President, Regulatory Affairs
520 Lake Cook Road, Suite 500
Deerfield, IL 60015

Dear Mr. Ford:

Please refer to your supplemental new drug application (sNDA), dated and received on May 8, 2019, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Xermelo (telotristat ethyl) tablets.

This Prior Approval sNDA provides for the following updates to the Prescribing Information based upon studies completed to fulfill postmarketing requirements (3152-1 through 3152-5) along with a postmarketing commitment (3152-6) and a pharmacokinetic study in subjects with renal impairment:

- Added a potential drug interaction with CYP2B6 substrates as a subsection to Drug Interactions.
- Revised the information on renal impairment and hepatic impairment to the respective subsections in Use in Specific Populations and Clinical Pharmacology, Pharmacokinetics.
- Added *in vitro* and *in vivo* drug interaction data to the Pharmacokinetics subsection of Clinical Pharmacology.
- Added results of a 2-year carcinogenicity study to Nonclinical Toxicology.

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

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

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 (MS) 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 MS Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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 Benjamin Vali, Regulatory Project Manager, at 301-796-4261 or Benjamin.vali@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director for Safety
Division of Gastroenterology
Office of Immunology and Inflammation
Center for Drug Evaluation and Research

Enclosures:
Content of Labeling:
Prescribing Information

[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.

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/

JOYCE A KORVICK
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