NDA 208264/S-007

APPROVAL LETTER

Adienne SA
c/o Biologics Consulting Group Inc Attention:
Ellen Iwudibia
Sr. Regulatory Affairs Manager
100 Daingerfield Road Suite 400
Alexandria, VA 22314

Dear Ellen Iwudibia:

Please refer to your Supplemental New Drug Application (sNDA) dated and received May 7, 2024, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for TEPADINA (thiotepa) for injection.

We acknowledge receipt of your amendment dated June 24, 2025, which constituted a complete response to our September 30, 2025, action letter.

This Prior Approval supplemental new drug application provides for:

1. The addition of (b) (4) (b) (4) as an alternate site for the manufacturer, primary packaging, quality control testing (b) (4) and stability testing of the drug product TEPADINA 15 and 100 mg. This change is associated with other changes to the manufacturing process, changes to the analytical methods, and addition of suppliers for primary packaging materials.
2. Addition of (b) (4) (b) (4)) as an alternate quality control testing site for the drug product TEPADINA 15 and 100 mg.
3. Changes to the specifications for reconstituted drug product, extension of in-use period for the reconstituted and diluted drug product and corresponding changes to the Prescribing Information and the carton box of TEPADINA® 15 and 100 mg.

APPROVAL & LABELING

We have completed our review of this supplemental 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 http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. 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 titled *SPL Standard for Content of Labeling Technical Qs and As* at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via 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 MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, 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).

CARTON AND CONTAINER LABELS

Submit final printed carton and container labels that are identical to enclosed carton and container labels, 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 *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 208264/S-007.**" Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Dahlia A. Walters, Regulatory Business Process Manager, at (301) 796 - 8427.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, Ph.D.
Supervisor
Division of Product Quality Assessment IV
Office of Product Quality Assessment I
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):
Content of Labeling
Carton and Container Labeling

Ramesh Raghavachari

Digitally signed by Ramesh Raghavachari
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