NDA 208264/S-003

SUPPLEMENT APPROVAL

Adienne SA
c/o Biologics Consulting Group, Inc.
Attention: Norman Baylor
1555 King Street
Suite 300
Alexandria, VA 22314

Dear Mr. Baylor:

Please refer to your Supplemental New Drug Application (sNDA) dated July 16, 2019, received July 16, 2019, and your amendments, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for TEPADINA (thiotepa) for Injection, 15 mg/vial and 100 mg/vial.

We also refer to our approval letter dated March 13, 2020, which contained the following error: "The Prescribing Information changes from Supplement 3, approved on March 13, 2020 were not incorporated into the attached approval letter."

This replacement approval letter incorporates the correction of the error. The effective approval date will remain March 13, 2020, the date of the original approval letter.

This Prior Approval supplemental new drug application provides for addition of (b) (4) (b) (4) a new drug product manufacturer and (b) (4) (b) (4) a new secondary packager specifically for drug products manufactured using the drug substance from (b) (4).

APPROVAL&LABELING

We have completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

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 "Prior Approval" (PAS) 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).

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 Chelsea Bostic, Regulatory Business Process Manager, at (301) 796 - 8862.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, Ph.D.
Chief, Branch I
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure (s):
Content of Labeling

Ramesh Raghavachari

Digitally signed by Ramesh Raghavachari
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