



NDA 020637/S-029

SUPPLEMENT APPROVAL

Arbor Pharmaceuticals, LLC
Attention: Briana Warren
Manager, Regulatory Affairs, Labeling
6 Concourse Parkway, Suite 1800
Atlanta, GA 30328

Dear Ms. Warren:

Please refer to your Supplemental New Drug Application (sNDA) dated and received June 8, 2018, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Gliadel Wafer (carmustine implant) 3.85% carmustine, 7.7 mg carmustine/Wafer.

This Prior Approval supplemental new drug application provides for the following updates to the U.S. package insert:

- To update the indication section to remove the word “malignant” from the newly-diagnosed high-grade glioma as an adjunct to surgery and radiation indication statement and to remove this terminology throughout the package insert; and, to remove the word “multiforme” from the recurrent glioblastoma as an adjunct to surgery indication statement and to remove this terminology throughout the package insert;
- To revise the Use in Specific Populations (8) section, to align with the Pregnancy and Lactation Labeling Rule (PLLR);
- To revise the Warnings and Precautions, Embryo-Fetal Toxicity (5.6) subsection to note that the recommended human dose for carmustine should be based on a body surface area;
- To revise the Clinical Pharmacology, Pharmacokinetics (12.3) subsection to include additional pharmacokinetic information regarding systemic absorption of carmustine; and,
- To revise the Clinical Pharmacology, Wafer Biodegradation (12.6) subsection to include updated biodegradation information.

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 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, and include the labeling changes proposed in any pending “Changes Being Effectuated” (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 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).

If you have any questions, please call Kelie Reece, Ph.D., Regulatory Health Project Manager, at (240) 402-6397.

Sincerely,

{See appended electronic signature page}

Jeffery Summers, M.D.
Deputy Director for Safety
Division of Oncology Products 2
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

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/

JEFFERY L SUMMERS
12/05/2018