DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022277/S-11

**CBE SUPPLEMENT ACKNOWLEDGEMENT/
SUPPLEMENT APPROVAL**

Merck, Sharp and Dohme Corporation
Attention: Margarita Parente
Senior Scientist, Global Regulatory Affairs
126 East Lincoln Avenue, P.O. Box 2000, RY34-B295
Rahway, NJ 07065-0900

Dear Ms. Parente:

Please refer to your Supplemental New Drug Application (sNDA) dated December 17, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Temodar (temozolomide), injection for intravenous use.

This supplemental application, submitted as a "Changes Being Effected" supplement, submitted in response to our November 24, 2015, Supplement Request letter, proposes to remove the statement informing healthcare providers of fatal reports associated with hepatitis B reactivation in the Patient Information Sheet.

APPROVAL & LABELING

This supplement has been reviewed under submission tracking number NDA 022277/11 in accordance with 21 CFR 314.70 and is approved effective this date.

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 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 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 includes 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).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, 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(s) 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, call Gina Davis, Senior Regulatory Health Project Manager, at (301) 796-0704.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE:
Patient Package Insert

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JEFFERY L SUMMERS
02/12/2016