NDA 022277/S-014

SUPPLEMENT ACKNOWLEDGMENT & APPROVAL

Merck Sharp & Dohme Corporation
A subsidiary of Merck & Company, Incorporated
Attention: Priyanka Vasabhaktula, Ph.D.
Associate Principal Scientist, Global Regulatory Affairs
351 North Sumneytown, Pike, UG2C-50
North Wales, PA 19454-2505

Dear Dr. Vasabhaktula:

We have received your supplemental new drug application (sNDA) submitted under section 505(b of the Federal Food, Drug, and Cosmetic Act (FDCA or the Act) for the following:

NDA NUMBER: 022277

SUPPLEMENT NUMBER: 014

PRODUCT NAME: Temodar (temozolomide), injection for invtravenous use

DATE OF SUBMISSION: October 27, 2020

DATE OF RECEIPT: October 27, 2020

We acknowledge receipt of your May 22, 2019, submission and your subsequent amendments regarding your request to update the pharmacist label. We also refer to our October 6, 2020, request for you to resubmit the pharmacist label as a prior approval supplemental new drug application.

This Prior Approval supplemental new drug application provides Pregnancy and Lactation Labeling Rule (PLLR)-related revisions to the pharmacist label.

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.

We note that your October 27, 2020, submission includes final printed labeling (FPL) for your Pharmacist label. We have not reviewed this FPL. You are responsible for assuring

that the wording in this FPL is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

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 Pharmacist label), 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.

If you have already submitted SPL please disregard the above.

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 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.

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

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}

Harpreet Singh, M.D.
Director, Division of Oncology 2
Office of Oncologic Diseases
Center for Drug Evaluation and Research

ENCLOSURE: Pharmacist Label

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/

B HARPREET SINGH
11/20/2020 04:23:46 PM