NDA 201532/S-020

SUPPLEMENT APPROVAL

Eisai Inc
Attention: Patricia Sass
Manager, Global Regulatory Strategy
155 Tice Blvd
Woodcliff Lake, NJ 07677

Dear Ms. Sass:

Please refer to your Supplemental New Drug Application (sNDA) dated and received August 21, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Halaven (eribulin mesylate) Injection.

This "Changes Being Effected in 30 Days" supplemental new drug application provides for revisions to the labeling to include sodium hydroxide as a pH adjuster.

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.

We note that your August 21, 2020, submission includes final printed labeling (FPL) for your prescribing information. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

Your commitment to provide the changes suggested in the IR issued on 02/17/2021 in two to four months as a PAS is acceptable. Please include the recommended change to revise the package type term throughout all labels and labeling from single-use to single-dose, as suggested in the IR issued on 02/08/2021, in the proposed PAS instead of the next annual report.

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

We acknowledge your August 21, 2020, submission containing final printed carton and container labeling.

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 Laya Keyvan, Regulatory Business Process Manager, at (240) 402 - 4598.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, Ph.D
Branch Chief, B1
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
Carton and Container Labeling

Ramesh Raghavachari

Digitally signed by Ramesh Raghavachari
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