DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 201532/S-004

Eisai, Inc.
Attention: Annmarie Petraglia
Senior Director, Global Regulatory Affairs
300 Tice Boulevard
Woodcliff Lake, NJ 07677

SUPPLEMENT APPROVAL

Dear Ms. Petraglia:

Please refer to your Supplemental New Drug Application (sNDA) dated September 7, 2011, received September 7, 2011 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Halaven (eribulin mesylate) Injection, 0.5mg/mL (1.0 mg/2 mL solution).

We acknowledge receipt of your amendments dated September 9 and December 8, 2011, January 9, January 23 and February 15, 2012.

This Prior Approval supplemental new drug application provides for revisions to Section 7, Effects of other Drugs on Halaven, of the package insert to include the effect of rifampin on the pharmacokinetics of eribulin. In addition, the supplement provides for the following revisions:

1. Correction of the title of Section 5.3 in the Highlights section from “Use in Pregnancy” to “Embryo-Fetal Toxicity.”

2. Relocation of pharmacokinetic information from section 8.6, Hepatic Impairment, to section 12.3, Pharmacokinetics, in a new subsection, Specific Populations, Hepatic Impairment.

3. Relocation of pharmacokinetics information from section 8.7, Renal Impairment, to section 12.3, Pharmacokinetics, in a new subsection, Specific Populations, Renal Impairment.

4. Deletion of section 12.2, Cardiac Electrophysiology and relocation of the information in a new section 12.6, Cardiac Electrophysiology.

5. Relocation of information under section 12.3 related to drug interactions from the subsection, "Metabolism" to the new subsection, "Drug Interactions."

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 package insert, 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 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 Vaishali Jarral, Regulatory Project Manager, at (301) 796-4248.

Sincerely,

{See appended electronic signature page}

Patricia Keegan, M.D.
Director
Division of Oncology Products 2
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research

ENCLOSURE: Package Insert
Patient Information Sheet

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

/s/

PATRICIA KEEGAN
02/17/2012