DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021055/S-008

SUPPLEMENT APPROVAL

Eisai Inc.
Attention: Lee Scaros, Pharm.D.
Director, Eisai Product Creations Systems
300 Tice Blvd.
Woodcliff Lake, NJ 07677

Dear Dr. Scaros:

Please refer to your Supplemental New Drug Application (sNDA) dated December 2, 2011, received December 5, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Targretin® (bexarotene) 75 mg Capsules.

We acknowledge receipt of your amendment dated December 19, 2011.

This "Changes Being Effected" supplemental new drug application provides for updates to the Clinical Pharmacology section of the label as requested in our Supplement Request letter issued October 3, 2011. These changes were based upon the review of February 24, 2010 submission reporting on Postmarketing Commitment 1397- 4.

We have completed our review of this supplemental application. 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), 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).

POSTMARKETING COMMITMENTS SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B

We remind you of your postmarketing commitment which is still pending: 1397 – 1

To conduct a randomized controlled clinical trial in patients with cutaneous T-cell lymphoma. The trial should compare three dose levels of Targretin. We agree with your proposed doses of 125, 300, and 400 mg/m^2. The primary endpoint should be tumor response according to the Physician's Global Assessment, the Composite Assessment of Index Lesion Severity and the percent Body Surface Area Involvement with tumor. Tumor responses must be documented with photographs of index lesions and full body photographs (front and back). Time to tumor response, time to tumor progression and tumor response duration should also be assessed. The effect on pruritis and other tumor specific symptoms should be assessed. The trial must be conducted in the same patient population for which the drug is approved. Quality of life should also be assessed. Agreed upon dates for this trial are as follows: the trial should be initiated with 3 months of protocol finalization; patient accrual should be completed 3.5 years after study initiation; the study results and analysis should be submitted to the Agency within 9 months of the date that all patients remaining on the study have been followed for at least 24 weeks. Bone mineral density testing will be conducted in a cohort of these study patients.

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 Theresa Ferrara, Regulatory Project Manager, at (301) 796-2848.

Sincerely,

{See appended electronic signature page}

Ann T. Farrell, M.D.
Division Director
Division of Hematology Product
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 and this page is the manifestation of the electronic signature.

/s/

ANN T FARRELL
01/06/2012