



BLA 125427/S-094

SUPPLEMENT APPROVAL

Genentech, Inc.
Attention: Monica Shah
Regulatory Program Management
1 DNA Way
South San Francisco, CA 94080-4990

Dear Ms. Shah:

Please refer to your Supplemental Biologics License Application (sBLA), dated October 29, 2015, received October 29, 2015 submitted under section 351(a) of the Public Health Service Act for Kadcyra[®] (ado-trastuzumab emtansine), sterile lyophilized single use vial, 100 mg and 160 mg vials (20 mg/mL).

We also refer to our approval letter dated April 28, 2016, which contained the following error:

- Language regarding hepatic impairment [REDACTED] (b) (4) [REDACTED] was inadvertently included in the approved labeling for Supplement 094.

This replacement approval letter incorporates the correction of the error. The effective approval date will remain April 28, 2016, the date of the original approval letter.

This “Prior Approval” supplemental biologics application proposes updates to the Use in Specific Populations section of the Full Prescribing Information (FPI) in compliance with the new content and format requirements of the Pregnancy and Lactation Labeling Rule.

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 text and with the minor editorial revision listed below and indicated in the enclosed labeling.

- In Highlights under Recent Major Changes, “Boxed Warning” with date is added to reflect the change made to the last bullet of the Boxed Warning.
- In the FPI, a margin mark was added to the last bullet of the Boxed Warning to indicate the Recent Major Change.

- Margin marks were removed in sections 8 (Use in Specific Populations) and 17 (Patient Counseling Information). Margin marks are only used to denote Recent Major Changes in sections 1-5 of the FPI.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical to the enclosed labeling (text for the package insert) and include the labeling changes proposed in any pending “Changes Being Effected” (CBE) supplements. 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/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this BLA, including pending “Changes Being Effected” (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 601.12(f)] in MS Word format that includes the changes approved in this supplemental application.

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.

All promotional materials for your drug product that include representations about your drug product must be promptly revised to make it consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 601.12(a)(4)]. The revisions to your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 601.12(a)(4) to the address above, by fax to 301-847-8444, or electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf>).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved BLA (in 21 CFR 600.80 and in 21 CFR 600.81).

If you have any questions, call Rajesh Venugopal, Senior Regulatory Project Manager, at (301) 796-4730.

Sincerely,
{See appended electronic signature page}

Geoffrey Kim, MD
Director
Division of Oncology Products 1
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research

ENCLOSURE(S):
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/

GEOFFREY S KIM
04/28/2016