DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 125427/14

SUPPLEMENT APPROVAL

Genentech
Attention: Patrick Leong
1 DNA Way
South San Francisco, California 94080

Dear Mr. Leong:

Please refer to your Supplemental Biologics License Application (sBLA), dated May 14, 2013, received May 14, 2013, submitted under section 351(a) of the Public Health Service Act for Kadcyla™ (ado-trastuzumab emtansine).

This "Changes Being Effected" supplemental biologics application, which proposes to update the carton labeling with the revised statements "**The vial is manufactured under partial vacuum, which may or may not pull diluent into the vial during reconstitution. Diluent should be slowly injected into the vial.**", and the Final Dear Pharmacist Letter to provide the rationale of the revised carton labeling has been approved.

This supplemental biologics application provides for revisions to the carton labeling for Kadcyla™ (ado-trastuzumab emtansine).

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.

Submit final printed carton and container labels that are identical to the enclosed draft labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labels for approved STN BL 125427/014**." Approval of this submission by FDA is not required before the labeling is used.

This information will be included in your biologics license application file.

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 Kim Robertson, Regulatory Project Manager, at (301) 796-1441.

Sincerely,

{See appended electronic signature page}

Kathleen A. Clouse, Ph.D.
Director
Division of Monoclonal Antibodies
Office of Biotechnology Products
Center for Drug Evaluation and Research

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

/s/

KATHLEEN A CLOUSE STREBEL
08/29/2013