DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 125427/12

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 April 8, 2013, received April 9, 2013, submitted under section 351(a) of the Public Health Service Act for Kadcyla™ (Ado-trastuzumab emtansine).

This "Changes Being Effected" supplemental biologics application proposes to update the US package insert (USPI) to include proposed changes to Section 2.3. Proposed new language:

1. Administer KADCYLA as an intravenous infusion only with a 0.22 micron in-line polyethersulfone (PES) filter. Do not administer as an intravenous push or bolus.
2. The reconstituted lyophilized vials should be used immediately following reconstitution with Sterile Water for Injection. If not used immediately, the reconstituted KADCYLA vials can be stored for up to 24 hours in a refrigerator at 2ºC to 8ºC (36°F to 46°F); discard unused KADCYLA after 24 hours. *Do not freeze.*
3. The diluted KADCYLA infusion solution should be used immediately. If not used immediately, the solution may be stored in a refrigerator at 2ºC to 8ºC (36°F to 46°F) for up to 24 hours prior to use. This storage time is additional to the time allowed for the reconstituted vials. *Do not freeze or shake.*

This supplemental biologics application provides for revisions to the 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.

We note that your May 13, 2013 submission includes final printed labeling (FPL) for your package insert. 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.

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 Lisa Skarupa, Regulatory Project Manager, at (301) 796-2219.

Sincerely,

{See appended electronic signature page}

Kathleen Clouse, Ph.D.
Director
Division of Monoclonal Antibodies
Office of Biotechnology 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/

KATHLEEN A CLOUSE STREBEL
08/19/2013