DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 125409/S-109

SUPPLEMENT APPROVAL

Genentech, Inc.
Attention: Ardelle (Jia) Ying, M.D., Ph.D.
Associate Program Director, Global Regulatory Affair (PDR-PM)
1 DNA Way
South San Francisco, CA 94080

Dear Dr. Ying:

Please refer to your Supplemental Biologics License Application (sBLA), dated October 23, 2015, received October 23, 2015, and your amendments, submitted under section 351(a) of the Public Health Service Act for Perjeta® (pertuzumab).

This Prior Approval supplemental biologics application provides for changes to the USE IN SPECIFIC POPULATIONS, Section 8 of the Full Prescribing Information to comply with the new content and format requirements of the Pregnancy and Lactation Labeling Rule (PLLR). Also, where appropriate, the language and content of Section 8 has been aligned with the Herceptin® and Kadcyla® Full Prescribing Information.

APPROVAL & LABELING

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, 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.

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, contact Amy Tilley, Regulatory Project Manager, at 301-796-3994 or amy.tilley@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Geoffrey Kim, M.D.
Director
Division of Oncology Products 1
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/

GEOFFREY S KIM
03/22/2016