DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 103792/S-5345

SUPPLEMENT APPROVAL

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

Dear Ms. Guy:

Please refer to your Supplemental Biologics License Application (sBLA), dated September 27, 2018, received September 27, 2018, and your amendments, submitted under section 351(a) of the Public Health Service Act for Herceptin® (trastuzumab) for Injection, 150 mg lyophilized powder in a single-dose vial for reconstitution and 420 mg lyophilized powder in a multiple-dose vial for reconstitution.

This Prior Approval Supplement (PAS) was submitted in response to the agency's Supplement Request letter dated May 11, 2018. The basis for the agency's request was due to the interchangeable use of the terms 'cake' and 'powder' throughout the prescribing information (PI), in reference to the drug product (DP). This supplement proposes revisions to the Prescribing Information to more adequately describe the appearance of the DP before and during reconstitution to avoid end user confusion. Revisions were proposed to Sections 2.4, 3, 11, and 16.1 of the 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.

Please note that the attached labeling corrects the spelling of the word "dilent" to "diluent" in Subsection 2.4, 150 mg Single-dose vial Reconstitution paragraph, first bullet.

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 Prescribing Information 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 include 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 Microsoft Word format that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), 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).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), 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.

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 Amy Tilley, Regulatory Project Manager, at 301-796-3994.

Sincerely,

{See appended electronic signature page}

Laleh Amiri-Kordestani, MD
Supervisory Associate Director
Division of Oncology Products 1
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research

ENCLOSURE:
Prescribing Information

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

LALEH AMIRI KORDESTANI
11/29/2018