DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

BLA 125085/S-329

SUPPLEMENT APPROVAL

Genentech Inc
Attention: Christy Rolfson
Pharma Technical Regulatory
1 Antibody Way
Oceanside, CA 92056

Dear Ms. Rolfson:

Please refer to your Supplemental Biologics License Application (sBLA) dated October 4, 2018, received October 4, 2018, and your amendments, submitted under section 351(a)of the Public Health Service Act for Avastin (bevacizumab) injection.

We also refer to our approval letter dated April 3, 2019, which did not include the labeling section of the action.

This replacement approval letter incorporates the correction of the error. The effective approval date will remain April 3, 2019, the date of the original approval letter.

This "Changes Being Effected in 30 days" supplemental biologics license application provides for the (b) (4) bevacizumab drug substance manufacturing process at the Oceanside drug substance manufacturing facility (FEI:3006129086).

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective from the April 3, 2019, approval letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions indicated in the enclosed labeling.

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, 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).

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

If you have any questions, call Andrew Shiber, Regulatory Business Process Manager, at (301) 796 - 4798.

Sincerely,

{See appended electronic signature page}

Kathleen A. Clouse, Ph.D.
Director
Division of Biotechnology Review and Research I
Office of Biotechnology Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling
Prescribing Information

Kathleen
Clouse Strebel

Digitally signed by Kathleen Clouse Strebel
Date: 5/08/2019 04:35:08PM
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