DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 125085/208

SUPPLEMENT BLA APPROVAL

Genentech, Incorporated
Attention: Michelle Rohrer, Ph.D.
Vice President, Regulatory Affairs
1 DNA Way MS# 241B
South San Francisco, CA 94080

February 8, 2011

Dear Dr. Rohrer:

Please refer to your Supplemental Biologics License Application (sBLA), dated August 23, 2010, received August 24, 2010, submitted under section 351 of the Public Health Service Act for Avastin (bevacizumab).

We acknowledge receipt of your amendments dated September 2, October 19, and November 16, 2010, and January 12, 2011.

This "Prior Approval" labeling supplement to your biologics license application revises the CLINICAL STUDIES, Unresectable Non-Squamous Non-Small Cell Lung Cancer subsection to include the overall survival results of study BO17704 and revises the INDICATIONS AND USAGE, Glioblastoma and the USE IN SPECIFIC POPULATIONS, Pediatric Use subsections.

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.

In addition, post-marketing commitment #1 under STN 125085/85 approved on October 11, 2006, is now fulfilled. You are no longer required to report on this commitment.

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 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/U

CM072392.pdf. For administrative purposes, please designate this submission "**Product Correspondence – Final SPL for approved BLA STN 125085/208**."

Also within 14 days, amend all pending supplemental applications 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.

The SPL will be accessible via publicly available labeling repositories.

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, please call Ms. Sharon Sickafuse, Senior Regulatory Health Project Manager, at (301) 796-2320.

Sincerely,

/Patricia Keegan/
Patricia Keegan, M.D.
Director
Division of Biologic Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

ENCLOSURE: Revised Package Insert