



BLA 125085/238

SUPPLEMENT APPROVAL

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

Dear Dr. Rohrer:

Please refer to your Supplemental Biologics License Application (sBLA), dated December 1, 2011, received December 1, 2011, submitted under section 351 of the Public Health Service Act for Avastin (bevacizumab).

We acknowledge receipt of your amendments dated January 5, 19, 23, 30, and 31, February 21, and April 12, and 17, 2012.

This "Changes Being Effected" labeling supplement to your biologics license application revises the package insert to provide updated information regarding congestive heart failure in the ADVERSE REACTIONS, Clinical Trial Experience (6.1) subsection and to add hepatobiliary disorders, gallbladder perforation to the ADVERSE REACTIONS, Postmarketing Experience (6.3) subsection

PRODUCT LABELING

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.

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/U>

[CM072392.pdf](#). For administrative purposes, please designate this submission “**Product Correspondence – Final SPL for approved BLA STN 125085/238.**”

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.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, 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, please call Ms. Sharon Sickafuse, Senior Regulatory Health Project Manager, at (301) 796-2320.

Sincerely,

{See appended electronic signature page}

Patricia Keegan, M.D.
Director
Division of Oncology Products 2
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/

PATRICIA KEEGAN
05/03/2012