DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 125147/186

SUPPLEMENT APPROVAL

Amgen, Inc.
Attention: Thomas DeMelfi, Jr.
Senior Manager, Regulatory Affairs
One Amgen Center Drive
Thousand Oaks, CA 91320-1799

Dear Mr. DeMelfi:

Please refer to your Supplemental Biologics License Application (sBLA), dated November 22, 2013, received November 22, 2013, submitted under section 351(a) of the Public Health Service Act for Vectibix (panitumumab).

We acknowledge receipt of your amendments dated December 9, 2014, February 4, 2014, February 10, 2014, February 12, 2014, March 17, 2014, March 21, 2014, March 24, 2014, April 25, 2014, May 12, 2014, May 14, 2014, May 19, 2014 May 21, 2014 and May 22, 2014.

This Prior Approval supplemental biologics application provides for a new clinical indication for Vectibix, as monotherapy, for the treatment of patients with wild-type *KRAS* (exon 2 in codons 12 or 13) metastatic colorectal cancer (mCRC), as determined by an FDA-approved test for this use, following disease progression on fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy regimens.

APPROVAL & 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/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.

SUBPART E FULFILLED

We approved this BLA under the regulations at 21 CFR 601 Subpart E for Accelerated Approval of Biological Products for Serious or Life-Threatening Illnesses. Approval of this supplement fulfills your commitments made under 21 CFR 601.41.

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.

We are waiving the pediatric studies requirement for this application because necessary studies are impossible or highly impracticable because the disease/condition is very infrequent in children.

FULFILLMENT OF POSTMARKETING REQUIREMENT(S)/COMMITMENT(S)

We have received your submission dated November 22, 2013, containing the final report for the following postmarketing requirement (PMR) listed in the September 27, 2006 approval letter for BLA 125147/0.

PMR 1

> "To submit a final study report for study 20050181, entitled, "A Randomized, Multicenter Phase 3 Study to Compare the Efficacy of Panitumumab in Combination with Chemotherapy to the Efficacy of Chemotherapy Alone in Patients with Previously Treated Metastatic Colorectal Cancer" which is intended to verify the clinical benefit of Panitumumab through demonstration of an effect on overall survival (OS). This protocol was accepted for Special Protocol Assessment on May 3, 2006. Patient accrual began on June 30, 2006, and will be completed by September 30, 2009. The final study report will be submitted by March 30, 2010."

The study originally intended to fulfill PMR 1, study 20050181, was inadequate. The studies used to verify clinical benefit of Vectibix are study 20080763 entitled: "A Randomized, Multicenter, Open-label, Phase 3 Study to Compare the Efficacy and Safety of Panitumumab and Cetuximab in Subjects with Previously Treated, Wild-type *KRAS*, Metastatic Colorectal Cancer", and the updated results of Study 20050203 entitled "A Randomized, Multicenter, Phase 3 Study to Compare the Efficacy of Panitumumab in Combination with Oxaliplatin/5-fluorouracil/leucovorin to the Efficacy of Oxaliplatin/5-fluorouracil/leucovorin Alone in Patients with Previously Untreated Metastatic Colorectal Cancer."

We have reviewed your submission and conclude that the above requirement is fulfilled.

We remind you that there are postmarketing commitments listed in the September 27, 2006 approval letter that are still open.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 601.12(f)(4), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf. Information and Instructions for completing the form can be found at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

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 Melanie Pierce, Senior Regulatory Health Project Manager, at (301) 796-1273.

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
05/23/2014