DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 103795/S-5551

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING COMMITMENT

Amgen, Inc.
One Amgen Center Drive
Mail Stop 17-2-C
Thousand Oaks, CA 91320-1799

Attention: Shirin Grossman, RAC
Manager, Regulatory Affairs

Dear Ms. Grossman:

Please refer to your Supplemental Biologics License Application (sBLA), dated January 14, 2015, received January 14, 2015, and your amendments, submitted under section 351(a) of the Public Health Service Act for Enbrel (etanercept) for suspension 25 mg, solution in single-use prefilled syringe at 25 mg/mL and 50 mg/mL, and single-use SureClick auto-Injector at 50 mg/mL.

We acknowledge receipt of your amendment dated September 1, 2016, which constituted a complete response to our March 15, 2016, action letter.

This Prior Approval supplemental biologics application provides for the addition of the results of the pregnancy registry to the prescribing information.

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 prescribing information, text for the instructions for use, and the Medication Guide) 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 MS Word format that includes the changes approved in this supplemental application.

FULFILLMENT OF POSTMARKETING COMMITMENT

We have received your submission dated November 14, 2014, containing the final report for the following postmarketing commitment listed in the March 4, 2004, approval letter for BLA 103795/5149.

2541-4 To conduct a prospective, observational registry study of women with rheumatoid arthritis, juvenile rheumatoid arthritis, psoriatic arthritis and plaque psoriasis exposed to Etanercept during pregnancy or within two weeks prior to conception. This study will assess the outcomes in the offspring born to those women who were exposed to Etanercept during pregnancy relative to background risk in similar patients not exposed to Etanercept. These outcomes will include adverse effects such as major birth defects (congenital anomalies), minor birth defects, fetal size in relation to gestational age, birth weight, developmental milestones, malignancies, serious infections, premature delivery and pre-eclampsia, spontaneous abortions and still births and will be assessed in the first year after birth for infants prenatally exposed to Etanercept. A final protocol will be submitted by December 31, 2004, that will include the revised draft labeling with the inclusion of the pregnancy registry telephone number. The study will be initiated by March 31, 2005, patient accrual will be completed by March 31, 2010, the study will be completed by December 31, 2011, and the final study report will be submitted by September 30, 2012.

We have reviewed your submission and conclude that the above commitment was fulfilled.

This completes all of your postmarketing requirements and postmarketing commitments acknowledged in our March 4, 2004, letter for BLA 103795/S-5149.

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, call Carol F. Hill, Senior Regulatory Health Project Manager for Safety, at (301) 796-1226.

Sincerely,

{See appended electronic signature page}

Sally Seymour, MD
Deputy Director for Safety
Division of Pulmonary, Allergy, and Rheumatology Products
Office of Drug Evaluation II
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/

SALLY M SEYMOUR
07/11/2017