DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 103976/5161

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING COMMITTMENT

Genentech
1 DNA Way
South San Francisco, California 94080

Attention: Cindy Wilson
Regulatory Program Management

Dear Ms. Wilson:

Please refer to your Supplemental Biologics License Applications (sBLA) dated October 30, 2009, received February 26, 2014, submitted under section 351(a) of the Public Health Service Act for Xolair (omalizumab).

We acknowledge receipt of your amendments dated January 22, March 5, April 15 (2), July 12, August 17, and 27, September 15, November 5, and 8, and December 3, 2010, and February 4, April 18, and 21, June 8, and October 27, 2011, and January 13, May 31, June 27, September 12, November 15, and December 21, 2012, and August 9, and September 16, 2013, and January 21, and 23, February 24, and 26, April 11, May 20, and 29, and June 10, July 11, August 20, and 28, and September 11, and 24, 2014.

These Prior Approval supplemental biologics applications provide for labeling changes to the package insert to include EXCELS study data from your post marketing study.

APPROVAL & LABELING

We have completed our review of these supplemental applications, 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 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 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.

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.

FULFILLMENT OF POSTMARKETING COMMITMENT

Your submission dated December 21, 2012, contained the final report for the following postmarketing commitment listed in the June 20, 2003, approval letter for BLA 103976/0.

PMC#3 To conduct a prospective, observational cohort study of 5,000 Omalizuamb-treated and 2,500 untreated patients that assess the clinical safety of Omalizumab by determining the incidence of malignancy and other serious adverse events (SAEs) in Omalizumab-treated patients with moderate to severe persistent asthma and skin test or *in vitro* reactivity to an aeroallergen compared with patients not treated with Omalizumab. Study subjects will be followed for at least 5 years, and Omalizumab-treated patients will be matched at enrollment to untreated patients by age, gender, and race/ethnicity. Interim reports will be filed yearly. The final protocol of the study will be submitted to FDA by December 31, 2003, patient accrual will be completed by March 31, 2006, the study will be completed by March 31, 2011, and a final study report will be submitted to the FDA by September 30, 2011.

We have reviewed your submission and conclude that the above commitment was fulfilled. We remind you that there are postmarketing commitments listed in the June 20, 2003 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 Colette Jackson, Senior Regulatory Health Project Manager, at (301) 796-1230.

Sincerely,

{See appended electronic signature page}

Sally Seymour, M.D.
Deputy Director of 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
09/26/2014