DEPARTMENT OF HEALTH AND HUMAN SERVICES

**Food and Drug Administration**
**Silver Spring MD 20993**

Our STN: BL 103976/5166

**APPROVAL**
January 4, 2010

Genentech Inc.
1 DNA Way
South San Francisco, California 94080-4990

Attention: Todd W. Rich, M.D.
V.P., Clinical & Commercial Regulatory Affairs

Dear Dr. Rich:

Please refer to the supplement to your biologics license application, dated December 5, 2008, received December 5, 2008, submitted under section 351 of the Public Health Service Act for Xolair (omalizumab).

We acknowledge receipt of your amendments dated January 13, February 19, March 9, and 17, April 22, May 7, 8, 26, and 28, June 1, 2, July 15, August 31, October 28, and December 24, and 30, 2009, and January 4, 2010 (2).

This supplemental application provides for updates to the USE IN SPECIFIC POPULATIONS, Pediatric Use subsection to include the results of your pediatric studies as required under the Pediatric Research Equity Act (PREA) and provides for a revised labeling format to comply with the Physican's Labeling Rule.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with minor editorial revisions listed in the enclosed labeling.

## 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 study requirement for ages zero to 5 years of age because evidence strongly suggests that the product would be unsafe in this pediatric subpopulation.

We note that you have fulfilled the pediatric study requirement for ages 6-11 of age for this

application.

This product label has information covering ages 6 to 17 years for this indication. Therefore, no additional studies are needed in this pediatric group.

## CONTENT OF LABELING

Within 14 days of the date of this letter, submit 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 in content to, except for including the revisions indicated, the enclosed package insert. The content of labeling should be submitted by updating your application by referencing the SPL file submitted to the drug establishment registration and drug listing system. To do this, place a link in your application submission that directs FDA to your SPL file. For administrative purposes, please designate this submission "**Product Correspondence – Final SPL for approved BLA STN 103976/5166.**" For additional information on submitting labeling to drug establishment registration and drug listing and to applications, see the FDA guidances at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072339.pdf and http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

## 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
Division of Drug Marketing, Advertising, and Communications
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. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

**LETTERS TO HEALTH CARE PROFESSIONALS**

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to this BLA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

If you have any questions, call Colette Jackson, Senior Regulatory Health Project Manager, at (301) 796-1230.

Sincerely,

/Lydia Gilbert-McClain, M.D./
Lydia Gilbert-McClain on behalf of Badrul A. Chowdhury
Badrul A. Chowdhury, M.D., Ph.D.
Director
Division of Pulmonary and Allergy Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: Approved Labeling