DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 103976/5191

SUPPLEMENT BLA APPROVAL
RELEASE REMS REQUIREMENT
December 22, 2011

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

Attention: Michelle H. Rohrer, Ph.D.
Vice President, PDR Program Management

Dear Dr. Rohrer:

Please refer to your Supplemental Biologics License Application (sBLA), dated November 17, 2011, received November 18, 2011, submitted under section 351 of the Public Health Service Act for Xolair (omalizumab).

We acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated November 17, 2011.

This Prior Approval supplement to your biologics license application proposes to eliminate the requirement for the approved Xolair (omalizumab) REMS.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Xolair (omalizumab) was originally approved on July 24, 2009, and the most recent REMS modification was approved on December 21, 2010. The REMS consists of a Medication Guide, and a timetable for submission of assessments of the REMS.

You propose that FDA no longer require a REMS for Xolair (omalizumab).

We have determined that maintaining the Medication Guide as part of the approved labeling is adequate to address the serious and significant public health concern and meets the standard in 21 CFR 208.1. Therefore, it is no longer necessary to include the Medication Guide as an element of the approved REMS to ensure that the benefits of Xolair (omalizumab) outweigh its risks.

Therefore, we agree with your proposal, and a REMS for Xolair (omalizumab) is no longer required.

We remind you that the Medication Guide will continue to be part of the approved labeling in accordance with 21 CFR 208.

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 Project Manager, at (301) 796-1230.

Sincerely,

/ Sally Seymour /
Sally Seymour, M.D.
Deputy Director for Safety
Division of Pulmonary, Allergy, and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research