**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

STN 103976/5087

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

Attention: Patricia Harada
Regulatory Affairs

Dear Ms. Harada:

Please refer to your supplemental biologics license application dated September 12, 2005, received September 29, 2005, for Xoliar (omalizumab) to revise the "Precautions" and "Adverse Events" sections of the label.

We also acknowledge receipt of your submissions dated March 31, and April 2, 2006.

We completed our review of this supplemental application, as amended. This supplement has been approved, effective the dated of this letter for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the package insert submitted April 2, 2006. Please submit all final printed labeling at the time of use and include implementation information on FDA Form 356h. Please provide a PDF-format electronic copy as well as original paper copies (ten for circulars and five for other labels).

Please refer to http://www.fda.gov/cder/biologics/default.htm for important information regarding therapeutic biological products, including the addresses for submissions.

The address for all submissions to this application is:

Food and Drug Administration
Center for Drug Evaluation and Research
Therapeutic Biological Products Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

This information will be included in your biologics license application file.

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

Sincerely,

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