DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 125-156/S-087

SUPPLEMENT APPROVAL

Genentech, Inc.
Attention: Tania Gonzalez, Ph.D.
Regulatory Program Management
1 DNA Way, MS 241B
South San Francisco, CA 94080-4990

Dear Dr. Gonzalez:

Please refer to your Supplemental Biologics License Application (sBLA), dated September 7, 2012, received September 10, 2012, submitted under section 351(a) of the Public Health Service Act for Lucentis (ranibizumab injection).

We acknowledge receipt of your amendment dated March 4, 2013.

This "Prior Approval" supplemental biologics application provides for revised carton and vial labels for the 0.3 mg and 0.5 mg configurations of Lucentis.

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 and with the minor editorial revisions listed below.

> The vial label for the 0.3 mg dose appears to have a red line as part of the graphic. Please remove this red line in the Final Printed Labeling (FPL).

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels except with the revisions listed below, as soon as they are available, but no more than 30 days after they are printed.

> The vial label for the 0.3 mg dose appears to have a red line as part of the graphic. Please remove this red line in the Final Printed Labeling (FPL).

Please submit these labels electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may

submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. Approval of this submission by FDA is not required before the labeling is used.

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 regarding this supplemental application, please contact Ms. Leanna M. Kelly, Consumer Safety Officer, at (301) 796-0471. For all other inquiries regarding this BLA, call Ms. Judit Milstein, Chief, Project Management Staff, at (301) 796-0763.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, M.D.
Deputy Director
Division of Transplant and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE:
Carton and Container Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

WILEY A CHAMBERS
03/08/2013