DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 125156/105

SUPPLEMENT APPROVAL

Genentech, Inc.
Attention: Tammy Rose
Associate Director of Regulatory Affairs
1 DNA Way, MS 241B
South San Francisco, CA 94080-4990

Dear Ms. Rose:

Please refer to your Supplemental Biologics License Application (sBLA), dated February 18, 2014, and received February 18, 2014, submitted under section 351(a) of the Public Health Service Act for Lucentis (ranibizumab injection).

We acknowledge receipt of your amendments dated:

April 8, 2014 June 13, 2014 October 28, 2014

This Prior Approval supplemental biologics application provides for an update to the USPI to provide the physician and the patient with clinical information based on the efficacy results following Study FVF4168g and Study FVF4170g.

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.

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 Christina Marshall, Regulatory Project Manager, at (301) 796-3099.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, MD
Deputy Director
Division of Transplant and Ophthalmology Products
Office of Antimicrobial Products
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/

WILEY A CHAMBERS
11/25/2014