DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21-756/S-018

SUPPLEMENT APPROVAL

Eyetech Inc.
Attention: Bryan Bischel
Director, Medical and Regulatory Affairs
11360 Jog Road, Suite 200
Palm Beach Gardens, FL 33418

Dear Mr. Bischel:

Please refer to your Supplemental New Drug Application (sNDA) dated and received June 18, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Macugen (pegaptanib sodium injection) 0.3 mg.

We acknowledge receipt of your amendments dated May 11 and July 22, 2011.

The May 11, 2011, submission constituted a complete response to our February 11, 2011, action letter.

This "Prior Approval" supplemental new drug application provides for (1) modifying the current approved labeling to meet the Physician Labeling Rule format requirements, (2) adding a statement to the Preparation for Administration section, (3) revising the Pregnancy section, (4) revising the Pediatric Use section, and (5) changing the subheading numbers under the USE IN SPECIFIC POPULATIONS section to reflect the identifying numbers required in 21 CFR 201.56.

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.

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at

http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions regarding this supplemental application, call Ms. Leanna Kelly, Consumer Safety Officer, at (301) 796-0471. For all other inquiries regarding this NDA, please contact Mr. Michael Puglisi, Regulatory Project Manager, at (301) 796-0791.

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:
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
10/12/2011