DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-756/S-006
NDA 21-756/S-007

OSI Eyetech, Inc.
Attention: Christine Boisclair
Vice President, Global Regulatory Affairs
58 South Service Road, Suite 110
Melville, New York 11747

Dear Ms. Boisclair:

Please refer to the following supplemental new drug applications, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Macugen (pegaptanib sodium injection) 0.3 mg:

Supplement Number	Letter Date	Received Date
S-006	September 19, 2005	September 21, 2005
S-007	December 8, 2005	December 13, 2005

We acknowledge receipt of your February 9, 2006, amendment to S-007.

These "Changes Being Effected" supplemental new drug applications provide for changes to the **CONTRAINDICATIONS**, **PRECAUTIONS**, **ADVERSE EVENTS**, and **DOSAGE AND ADMINISTRATION** sections of the package insert labeling.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed draft labeling submitted on February 9, 2006.

The electronic labeling rule published December 11, 2003, (68 FR 69009) requires submission of labeling content in electronic format effective June 8, 2004. For additional information, consult the following guidances for industry regarding electronic submissions: *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999) and *Providing Regulatory Submissions in Electronic Format – Content of Labeling* (February 2004). The guidances specify that labeling is to be submitted in *pdf* format. To assist in our review, we request that labeling also be submitted in MS Word format. If formatted copies of all labeling pieces are submitted electronically, labeling does not need to be submitted in paper.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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, call Michael Puglisi, Project Manager, at (301) 796-0791.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, M.D.
Director
Division of Anti-Infective and
Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure

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

/s/

Janice Soreth

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