



NDA 21-756/S-004

NDA 21-756/S-005

Eyetechn Pharmaceuticals, Inc.
Attention: Meg Casais
Director, CMC Regulatory Affairs
Three Times Square, 12th Floor
New York, New York 10036

Dear Ms. Casais:

Please refer to your supplemental new drug applications dated July 19, 2005, received July 20, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Macugen (pegaptanib sodium injection) 0.3 mg.

We acknowledge receipt of your submission dated November 15, 2005.

These supplemental new drug applications provide for a new embossed syringe and revised 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 draft labeling, which was submitted on July 19, 2005.

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 (i.e., package insert, container labels, and carton labels) 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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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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) 796-1400.

Sincerely,

{See appended electronic signature page}

Linda L. Ng, Ph.D.
Chemistry Team Leader for the
Division of Anti-Infective and
Ophthalmology Products, HFD-520
DNDC III, Office of New Drug Chemistry
Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
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/s/

Linda Ng
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