021756 - Original Approval - Packa

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Approval Package for:

APPLICATION NUMBER:
21-756

Trade Name:	Macugen
Generic Name:	Pegaptanib sodium injection, 0.3 mg
Sponsor:	Eyetech Pharmaceuticals, Inc.
Approval Date:	December 17, 2004
Indications:	Provides for the use of Macugen (pegaptanib sodium injection) for the treatment of neovaxcular (wet) age-related macular degeneration.

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APPLICATION NUMBER:

21-756

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Reviews / Information Included in this NDA Review.	
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Pharmacology Review(s)	X
Statistical Review(s)	
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APPLICATION NUMBER:

21-756

APPROVAL LETTER(S)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-756

Eyetech Pharmaceuticals, Inc.
Attention: Loni da Silva
Vice President, Global Regulatory Affairs
Three Times Square
12th Floor
New York, New York 10036

Dear Ms. da Silva:

Please refer to your new drug application (NDA) dated June 17, 2004, received June 17, 2004, 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 submissions dated March 17, May 12 and 27, June 7, July 14 and 28, September 10, 13, 20, 22, 23, and 30, October 4, 5, 7, 15, and 29, November 10 (three), 12, 19, 22, and 23, and December 1, 6, 8, 10 (three), 13, 14 and 16, 2004.

This new drug application provides for the use of Macugen (pegaptanib sodium injection) for the treatment of neovascular (wet) age-related macular degeneration.

We completed our review of this application, as amended. It is 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 (package insert submitted December 10, 2004, carton and container labeling submitted December 16, 2004). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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.

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