CLINICAL PHARMACOLOGY REVIEW

BLA 125,422	Submission Date(s): December 18, 2013
Brand Name	Jetrea
Generic Name	Ocriplasmin
Reviewer	Yoriko Harigaya, Pharm.D.
Team Leader	Philip M. Colangelo, Pharm.D., Ph.D.
OCP Division	DCP IV
OND Division	DTOP
Sponsor	ThromboGenics
Submission Type	[redacted] (b) (4) Supplement – 25)
Formulation; Strength(s)	Solution for intravitreal injection; Ocriplasmin [redacted] (b) (4) of the diluted solution
Proposed Indications	[redacted] (b) (4)
Dosage and Administration	Administer a single intravitreal injection [redacted] (b) (4)

ThromboGenics has submitted BLA125,422/25 [redacted] (b) (4) for Jetrea™ (ocriplasmin) Intravitreal Injection 2.5mg/mL for [redacted] (b) (4) The proposed dosing regimen is ocriplasmin [redacted] (b) (4) given a single intravitreal injection [redacted] (b) (4)

BLA125,422 ocriplasmin was granted marketing authorization approval by the Agency on 17 October, 2012 for the treatment of symptomatic vitreomacular adhesion in adults as a single dose intravitreal injection of 0.125 mg. Currently, the sponsor has submitted the results of a small exploratory pediatric study in support of the postmarketing requirements listed in the Jetrea approval letter of October 17, 2012 provided by the Agency.

There was no new Clinical Pharmacology information provided, and no revisions to the Clinical Pharmacology sections of the currently approved Jetrea labeling are needed. Therefore, no Clinical Pharmacology review is needed.

Yoriko Harigaya, Pharm.D.
Reviewer
Clinical Pharmacology
DCP4/OCP/OTS

Concurrence _____.

Philip Colangelo, Pharm.D., Ph.D.
Team Leader
Clinical Pharmacology
DCP4/OCP/OTS

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/s/

YORIKO HARIGAYA
05/15/2014

PHILIP M COLANGELO
05/15/2014