DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 125422/S-038

SUPPLEMENT APPROVAL

ThromboGenics, Inc.
Attention: Rusty Johnson, Ph.D.
Director, Regulatory Affairs, US
101 Wood Avenue South, Suite 610
Iselin, NJ 08830

Dear Dr. Johnson:

Please refer to your Supplemental Biologics License Application (sBLA) August 22, 2016, received August 22, 2016, and your amendments, submitted under section 351(a) of the Public Health Service Act for Jetrea (ocriplasmin intravitreal injection), 2.5 mg/mL.

This "Prior Approval" supplemental biologics application proposes adding a 1.25 mg/mL formulation.

APPROVAL & LABELING

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 and with the minor editorial revisions listed below.

Under Highlights of Prescribing Information:

1. Removal of duplicate "for intravitreal injection" from product title
2. Addition of date of Recent Major Change
3. First use of "intraocular pressure" spelled out in Warnings and Precautions

Section 2:

4. Addition of vertical line on left edge for Recent Major Change

Section 8.4:

5. First use of "posterior vitreous detachment" spelled out in Pediatric Use

As soon as possible, but no later than 14 days from the date of this letter, submit, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling (text for the package insert) and include the labeling changes

proposed in any pending "Changes Being Effected" (CBE) supplements. 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/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this BLA, including pending "Changes Being Effected" (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 601.12(f)] in MS Word format that includes the changes approved in this supplemental application.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved BLA (in 21 CFR 600.80 and in 21 CFR 600.81).

If you have any questions, call Jacquelyn Smith, M.A., Senior Regulatory Project Manager, at (301) 796-1600.

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(S):
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
02/22/2017