DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 125422/25

SUPPLEMENT APPROVAL

ThromboGenics, Inc.
Attention: Rusty Johnson, PhD
Head of Regulatory Affairs, US
101 Wood Avenue South, Suite 610
Iselin, NJ 08830

Dear Dr. Johnson:

Please refer to your Supplemental Biologics License Application (sBLA), dated December 18, 2013, received December 19, 2013, submitted under section 351(a) of the Public Health Service Act, for Jetrea (ocriplasmin intravitreal injection), 2.5 mg/mL.

We acknowledge receipt of your amendments dated:

January 7, 2014
February 14, 2014 (2)
March 24, 2014
May 23, 2014 (2)

This supplemental application provides for revisions to the Pediatric Use section of the package insert to reflect the results from Clinical Study, TG-MV-009, titled "The MIC (Microplasmin In Children) Trial: A Randomized, Placebo-controlled, double-masked, Clinical Trial of Intravitreal Microplasmin in Infants and Children Scheduled for Vitrectomy."

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.

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.

FULFILLMENT OF POSTMARKETING REQUIREMENT

We note that this supplemental application contains the final report for the following postmarketing requirement listed in the October 17, 2012, approval letter.

1. The MIC (Microplasmin In Children) Trial: A Randomized, Placebo-controlled, double-masked, Clinical Trial of Intravitreal Microplasmin in Infants and Children Scheduled for Vitrectomy

We have reviewed your submission and conclude that the above requirement is fulfilled. This completes your postmarketing requirement acknowledged in our October 17, 2012, letter.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 601.12(f)(4), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf. Information and Instructions for completing the form can be found at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

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, MA, Senior Regulatory Project Manager, at 301-796-1600.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, MD
Deputy Director
Division of Transplant and Ophthalmology Products
Office of Antimicrobial Products
Office of New Drugs
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
06/13/2014