DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

Our STN: BL 125523/0

MAJOR AMENDMENT ACKNOWLEDGEMENT

ProFibrix, BV
Attention: Linda Zuckerman, PhD
The Medicines Company
1144 Eastlake Ave East, Suite 700
Seattle, WA 98109

Dear Dr. Zuckerman:

We received your October 17, 2014 amendment to your biologics license application (BLA) submitted under section 351 of the Public Health Service Act (42 U.S.C. 262) for Fibrin Sealant, Human Fibrinogen/Human Thrombin on October 17, 2014.

We consider your submission a major amendment under the reauthorization of the prescription drug user fee program in the *Food and Drug Administration Safety and Innovation Act* of 2012 and will add an additional three months to the time by which we should complete our review. Therefore, the action due date is May 2, 2015.

We will contact you regarding your proposed labeling no later than April 2, 2014. If post marketing study commitments (506b) are required, we will contact you no later than April 2, 2014.

If you have any questions, please contact the Regulatory Project Manager, Tracy Tilghman, at (240) 402- 8376.

Sincerely,

Basil Golding, MD
Director
Division of Hematology Research and Review
Office of Blood Research and Review
Center for Biologics
Evaluation and Research