

**From:** Do, Yu  
**To:** [Joan.robertson@grifols.com](mailto:Joan.robertson@grifols.com)  
**Subject:** Information Request (Response Due by Tuesday, June 20, 2017): Original BLA, BL 125640/0, Fibrin Sealant (Human), Instituto Grifols, S.A.  
**Date:** Tuesday, June 06, 2017 11:30:00 AM  
**Attachments:** [image001.png](#)  
**Importance:** High

---

Dear Ms. Robertson:

We are reviewing your original November 3, 2016, submission to BLA 125640 for Fibrin Sealant (Human). We determined that the following information, regarding your analytical procedure IG MA-000158E\_ING “(b) (4) in Fibrinogen by (b) (4), “ is necessary to continue our review:

1. Your current fibrinogen control (Lot (b) (4) diluted from (b) (4) Fibrinogen, Human Plasma) has the established (b) (4) limits of (b) (4), which fall below the LOQ of your assay ((b) (4)). This indicates that you cannot measure (b) (4) of this control with adequate accuracy and precision.

Please establish a new control that has (b) (4) above your LOQ for the accuracy check of this assay and submit the results for evaluation.

The review of this submission is ongoing, and issues may be added, expanded upon, or modified as we continue to review this submission. Please submit your response as an amendment to this file by June 20, 2017, referencing the date of this request. If you anticipate you will not be able to respond by this date, please contact the Agency immediately so a new response date can be identified.

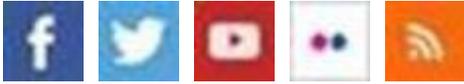
If we determine that your response to this information request constitutes a major amendment, we will notify you in writing.

The action due date for this file is November 3, 2017.

Please acknowledge receipt of this request and contact me at (240) 402-8343 or [Yu.Do@fda.hhs.gov](mailto:Yu.Do@fda.hhs.gov) if you have any questions.

Sincerely,

Yu Do, M.S.  
Regulatory Project Manager  
Office of Tissues and Advanced Therapies  
Center for Biologics Evaluation and Research  
Office of Medical Products and Tobacco  
Food and Drug Administration  
(240) 402-8343  
[Yu.Do@fda.hhs.gov](mailto:Yu.Do@fda.hhs.gov)



"THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone."