

**From:** [Do, Yu](#)  
**To:** [Joan.robertson@grifols.com](mailto:Joan.robertson@grifols.com)  
**Subject:** Information Request (Response Due by Thursday, October 19, 2017): Original BLA, BL 125640/0, Fibrin Sealant (Human), Instituto Grifols, S.A.  
**Date:** Monday, October 16, 2017 4:41:24 PM  
**Attachments:** [image002.png](#)  
**Importance:** High

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Dear Ms. Robertson:

We are reviewing your original November 3, 2016, submission to BLA 125640 for Fibrin Sealant (Human). We have the following comment and request for additional information to continue our review:

1. The following is our proposed language drafted for PREA Postmarketing Requirement with regard to BL 125640:

Instituto Grifols, S.A. commits to evaluating the safety and efficacy of FIBRIN SEALANT (Human) as an adjunct to hemostasis during surgery in pediatric patients < 18 years of age in the deferred pediatric clinical trial under protocol IG1405 entitled “A Prospective, Randomized, Active-Controlled, Single-blind, Parallel Group Clinical Trial to Evaluate the Safety and Efficacy of Fibrin Sealant Grifols (FS Grifols) as an Adjunct to Haemostasis during Surgery in Paediatric Subjects.” The study will include the Human Factors assessment under protocol IG\_PETC-000430\_ING entitled “Fibrin Sealant Grifols: Design for Human Factor Study,” which will have separate timelines as noted below.

Pediatric Study Initiation Date: January XX, 2018  
Pediatric Study Completion Date: June XX, 2023  
Pediatric Final Report Submission: June XX, 2024

Human Factors Study Initiation Date: January XX, 2018  
Human Factors Study Completion Date: January XX, 2018  
Human Factors Final Report Submission: April XX, 2018

Please submit the above timelines as a full date (e.g., June 30, 2023, instead of June 2023) and inform us in writing, upon review and internal discussion, if you agree with the proposed language and due dates. If not, please state accordingly and suggest alternatives for our consideration.

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 October 19, 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.

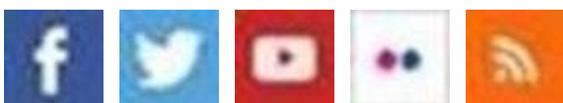
If we determine that your response to this information request constitutes a major amendment, we will notify you in writing.

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)



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