

**From:** Do, Yu  
**To:** [Joan.robertson@grifols.com](mailto:Joan.robertson@grifols.com)  
**Subject:** Information Request (Response Due by Thursday, December 8, 2016): Original BLA, BL 125640/0, Fibrin Sealant (Human), Instituto Grifols, S.A.  
**Date:** Friday, December 02, 2016 2:08:00 PM  
**Attachments:** [image001.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 determined that the following information is necessary to continue our review:

1. This is in reference to your December 2, 2016, submission as a response to our Information Request issued on November 22, 2016:

Your response to Design Control questions 2a through 2f is inadequate and not acceptable. Please provide specific response to each of these questions. If you don't have the requested information, please provide justification, a plan for implementation, and a timeline for corrective action.

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 December 8, 2016, 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  
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