

**From:** [Do, Yu](#)  
**To:** [Joan.robertson@grifols.com](mailto:Joan.robertson@grifols.com)  
**Subject:** Information Request (Response Due by Wednesday, October 25, 2017): Original BLA, BL 125640/0, Fibrin Sealant (Human), Instituto Grifols, S.A.  
**Date:** Friday, October 20, 2017 5:02:56 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 have the following comments and requests for additional information to continue our review:

1. Please describe in more detail all the testing that Grifols routinely performs on the incoming (b) (4) syringes, including the functionality test. Please specify the parameters assessed in the functionality test, and indicate the number of syringes used in this testing and the frequency of testing of incoming lots.
2. In regard to the application cannula, please describe the functional testing that is routinely performed on the incoming cannulas and indicate the number of samples taken to perform testing.

Additionally, you indicated that you do not perform sterility testing on the incoming cannulas. Please note that sterility of the cannula is considered a critical attribute; thus, as per 21 CFR 820.50, we recommend that you implement testing of the incoming cannula to verify the sterility as stated on Certificate of Analysis. Please comment.

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 25, 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

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