

From: [Do, Yu](#)
To: Joan.robertson@grifols.com
Subject: Information Request (Response Due by Thursday, September 28, 2017): Original BLA, BL 125640/0, Fibrin Sealant (Human), Instituto Grifols, S.A.
Date: Thursday, September 21, 2017 10:21:00 AM
Attachments: [image002.png](#)
Importance: High

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. The following is our proposed language drafted for a Postmarketing Commitment with regard to BL 125640:

Instituto Grifols, S.A. commits to providing results from small-scale studies for the (b) (4)

. The final results will be submitted as a "Postmarketing Study Commitment - Final Study Report" by August 31, 2018.

Please inform us in writing, upon review and internal discussion, if you agree with the proposed due date. If not, please state accordingly and suggest alternative date(s) for our consideration.

2. If there are known environmental isolates at the Instituto Grifols facility in Barcelona, Spain, we request the qualification in your sterility test (IG_IVMA-000281_ING and IG_IVMA-000203_ING) to indicate the suitability of your method for testing the Fibrinogen component and Thrombin component.

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 September 28, 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.

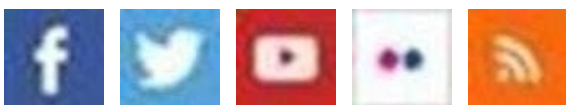
The action due date for this file is November 3, 2017.

Please acknowledge receipt of this request and contact me at (240) 402-8343 or Yu.Do@fda.hhs.gov 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



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