

From: [Do, Yu](#)
To: Joan.robertson@grifols.com
Subject: Information Request (Response Due by Friday, September 29, 2017): Original BLA, BL 125640/0, Fibrin Sealant (Human), Instituto Grifols, S.A.
Date: Tuesday, September 26, 2017 3:32:00 PM
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 have the following comment and requests for additional information to continue our review:

1. On all pages, please replace “STN/License No.:" with “cc: STN-0/License No.: _B or _FC.”
2. On page 1 of 6, please remove the Electronic Number line, as you must first start with paper submissions.

Once approved for electronic submission, this information should be included at the bottom of the page near the Authorized Official Signature.

3. On page 4 of 6 under Product Test Summary, please include MVD (Maximum Valid Dilution) above the result table.
4. On page 4 of 6 under Product Test Summary for Test Dilution, please delete (b) (4).

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 29, 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.

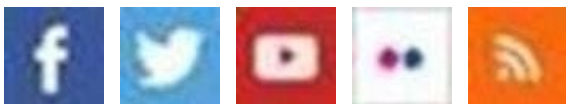
Please acknowledge receipt of this request and contact me at (240) 402-8343 or Yu.Do@fda.hhs.gov if you have any questions.

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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