

From: [Do, Yu](#)
To: Joan.robertson@grifols.com
Subject: Information Request (Response Due by Thursday, October 5, 2017): Original BLA, BL 125640/0, Fibrin Sealant (Human), Instituto Grifols, S.A.
Date: Tuesday, October 03, 2017 5:53:35 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 request for additional information to continue our review:

The alternative due date (i.e., December 31, 2018) proposed by Instituto Grifols, S.A. for submission of the “Postmarketing Study Commitment – Final Study Report” is acceptable. Our updated language for a Postmarketing Commitment (PMC) with regard to BL 125640 is as follows:

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 December 31, 2018.

Please provide written commitment to the PMC in your response upon review and internal discussions.

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 5, 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.

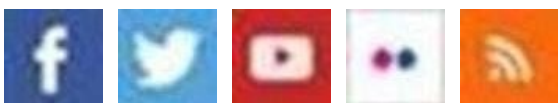
The action due date for this file is November 3, 2017.

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
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