

From: [Do, Yu](#)
To: Joan.robertson@grifols.com
Cc: kelly.smith@grifols.com
Subject: URGENT Information Request (Response Due by Friday, October 27, 2017): Original BLA, BL 125640/0, Fibrin Sealant (Human), Instituto Grifols, S.A.
Date: Wednesday, October 25, 2017 10:52:56 PM
Attachments: [image001.png](#)
[FDA Annotated Labeling Text Version October 25 2017 IG.docx](#)
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:

Please revise the Prescribing Information according to the attached annotated version of the labeling. Please accept all those tracked changes with which you agree, but insert your own comments where further discussion is warranted. Please indicate clearly, point by point, whether you would accept each change or not. If not, please provide a brief rationale or justification. Also, please be sure to submit in your response both clean and annotated versions of the revised labeling in Word and PDF files.

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 27, 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.

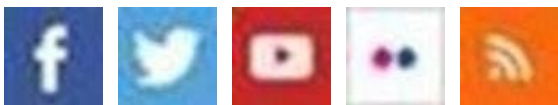
If we determine that your response to this information request constitutes a major amendment, we will notify you in writing.

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
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