

From: Do.Yu
To: Joan.robertson@grifols.com
Subject: Information Request (Response Due by Tuesday, October 24, 2017): Original BLA, BL 125640/0, Fibrin Sealant (Human), Instituto Grifols, S.A.
Date: Thursday, October 19, 2017 4:05:12 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 comments and requests for additional information to continue our review:

We note that your proposed language for the PREA PMR, submitted on October 18, 2017, did not state that the new Human Factors (HF) study will be conducted as a subpart of the pediatric trial IG1405. In addition, two separate paragraphs in your response for pediatric trial and HF, respectively, may be misconstrued as two different PMRs, which runs counter to our agreement of a single PREA PMR that includes the HF study as a subpart.

1. Please either revise your submission to state the language originally proposed by FDA (with your proposed timelines for each study) or modify your version so that it is consistent with the agreement reached during our Late-Cycle Meeting on August 31, 2017. Also, if there have been changes to your plan regarding the HF assessment, please provide your rationale or explanation for FDA to review.
2. Please revise your "Human Factors Final Report Submission" date to June 30, 2018, as that is the last day of the month in June.

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 24, 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.

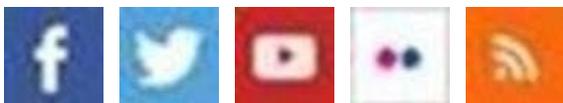
The action due date for this file is November 3, 2017.

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
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