

From: Do, Yu
To: Joan.robertson@grifols.com
Subject: Information Request (Response Due by Monday, September 11, 2017): Original BLA, BL 125640/0, Fibrin Sealant (Human), Instituto Grifols, S.A.
Date: Tuesday, August 29, 2017 4:43:00 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 comments and requests for additional information to continue our review:

We acknowledge receipt of your updated Lot Release Protocol template (August 4, 2017, amendment). Please further revise the Lot Release Protocol template to address our additional comments stated below:

1. On page 1 of 6, under “Source,” please state Human Plasma (U.S. Origin).
2. On page 1 of 6, under section “Summary of the History of Manufacture,” please include the definitions of “Total Filling Time” and “Total Processing Time” and their respective time limits, as recommended in the August 3, 2017, Information Request.
3. On page 1 of 6, please consider moving the information about Stabilizer to section “Summary of the History of Manufacture” (optional).
4. Throughout the Protocol, please use the proper name “Fibrin Sealant (Human).” Also, please do not use all capital letters for the word “Human” (“HUMAN”).
5. On pages 2 and 5 of 6, under “Appearance of Solution,” please use the USP terminology - “Colourless or pale solution essentially free of visible particulates” - to be consistent with your actual visual inspection. Alternatively, please justify in the response your position not to include the description “visible.”
6. On pages 2 and 5 of 6, please add the parameter “Sterility” to the lists of tests (in addition to the tables with detailed results).
7. Please add the maximum valid dilution to the “Product Test Summary” table for (b) (4) on pages 4 and 6.
8. Please change all EU/mL units in the document to IU/mL on pages 4 and 6.

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 11, 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,

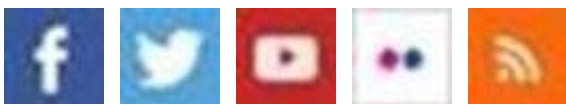
we will notify you in writing.

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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