

From: [Do, Yu](#)
To: [Robertson, Joan](#)
Subject: RE: 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 6:42:00 PM
Attachments: [image001.png](#)
[image002.jpg](#)
[image003.jpg](#)
[image004.jpg](#)
[image005.jpg](#)
[image006.jpg](#)
[image008.png](#)
[image009.jpg](#)
[image010.jpg](#)
[image011.jpg](#)
[image012.jpg](#)
[image024.jpg](#)
Importance: High

I apologize, Ms. Robertson, for the confusion. This is in reference to the Lot Release Protocol template. Thanks for checking and bringing this to my attention.

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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From: Robertson, Joan [mailto:Joan.Robertson@grifols.com]
Sent: Tuesday, September 26, 2017 5:10 PM
To: Do, Yu <Yu.Do@fda.hhs.gov>
Subject: RE: Information Request (Response Due by Friday, September 29, 2017): Original BLA, BL 125640/0, Fibrin Sealant (Human), Instituto Grifols, S.A.

Yu,

I acknowledge receipt.

I sent this to IG and they will likely understand the request; but to help me, can you tell me what documents you are referring to?

Thanks

Joan

Joan Robertson

Grifols Shared Services, NA
Vice President
Regulatory Affairs, Bioscience
Phone: (919) 359-7128
Mobile: (919) 308-9435
Fax: (919) 359-7304
8368 US 70 Bus. Hwy W
Clayton, NC, USA 27520

From: Do, Yu [<mailto:Yu.Do@fda.hhs.gov>]

Sent: Tuesday, September 26, 2017 3:32 PM

To: Robertson, Joan

Subject: Information Request (Response Due by Friday, September 29, 2017): Original BLA, BL 125640/0, Fibrin Sealant (Human), Instituto Grifols, S.A.

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) (redacted).

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
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