

From: Do, Yu
To: Joan.robertson@grifols.com
Subject: Information Request (Response Due by Thursday, August 17, 2017): Original BLA, BL 125640/0, Fibrin Sealant (Human), Instituto Grifols, S.A.
Date: Thursday, August 03, 2017 4:14:00 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, regarding the limit of quantitation (LOQ) determination for analytical procedure “(b) (4) [REDACTED] in Fibrinogen by (b) (4)” (IG MA-000158E_ING) and its validation, to continue our review:

1. Your response, submitted on February 23, 2017 (Amendment 12), to Item 1e of the January 31, 2017, Information Request is not acceptable. Please provide adequate characterization data to support that (b) (4) in the (b) (4) [REDACTED] is due to an (b) (4) [REDACTED] of fibrinogen. The (b) (4) [REDACTED] and (b) (4) [REDACTED] analyses of the (b) (4) [REDACTED] may provide such information.
2. You stated, “(b) (4) [REDACTED] of fibrinogen are considered (b) (4) [REDACTED].” Please provide supporting data or literature references to support this claim.

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 August 17, 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.
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