

From: Do, Yu
To: Joan.robertson@grifols.com
Subject: Information Request (Response Due by Wednesday, April 5, 2017): Original BLA, BL 125640/0, Fibrin Sealant (Human), Instituto Grifols, S.A.
Date: Monday, April 03, 2017 4:07:00 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 comment and request for additional information at this time:

This is in reference to the analytical procedure IG MA-000158E_ING entitled “(b) (4) [REDACTED] in Fibrinogen by (b) (4) [REDACTED]”:

You used a (b) (4) [REDACTED] in this procedure. However, we learned that this (b) (4) [REDACTED] was discontinued by the manufacturer in 2016 and has been replaced by (b) (4) [REDACTED].

1. Please provide us with a (b) (4) [REDACTED] if you have a stock. Please ship the requested (b) (4) [REDACTED] to the following address:

Hsiaoling Wang, PhD
WO 75, G662
10903 New Hampshire Ave.
Silver Spring, MD 20993

2. Alternatively, please confirm that use of (b) (4) [REDACTED] is appropriate for the assay. Along with confirmation, please submit appropriate comparability data to show that performance of these (b) (4) [REDACTED] are equivalent. 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 April 5, 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
Yu.Do@fda.hhs.gov



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