

From: Do, Yu
To: Joan.robertson@grifols.com
Subject: Information Request (Response Due by Friday, August 4, 2017): Original BLA, BL 125640/0, Fibrin Sealant (Human), Instituto Grifols, S.A.
Date: Tuesday, July 25, 2017 9:33:00 AM
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:

1. Under Section 3.2.P.2.4 Container closure system (reports IG_ITEC-002201_ING v1 and IG_ITEC-002265_ING v2) for both fibrinogen and thrombin, you stated that (b) (4) and (b) (4) were analyzed “according to IG_MA-000678,” and (b) (4) were analyzed “according to TO-MA-0174-1.” However, you did not include the referenced documents.

Please submit the documents IG_MA-000678 and TO-MA-0174-1 to facilitate review.

2. In your submission, you provided risk assessments on extractables and leachables (E&L) only for the final drug product (FDP) containers (for each of its components, fibrinogen and thrombin). However, you did not provide risk assessments on the E&L from materials, such as columns, resins, filters, and membranes, used at various manufacturing steps before filling the product into its final container.

Please provide results from studies assessing the levels of E&L in the FDP, and the risk assessments of leachables that may be present in the FDP from materials used in different unit operations of the manufacturing process.

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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 4, 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

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