

From: Do, Yu
To: Joan.robertson@grifols.com
Subject: Information Request (Response Due by Wednesday, April 26, 2017): Original BLA, BL 125640/0, Fibrin Sealant (Human), Instituto Grifols, S.A.
Date: Tuesday, April 18, 2017 3:24:00 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 determined that the following information is necessary to continue our review:

1. To better estimate the potential virus load in the starting material, please submit the *Limit of Detection* of each of the Nucleic Acid Tests (NAT) used for detection of Human Immunodeficiency Virus, Hepatitis B Virus, Hepatitis C Virus, Hepatitis A Virus, or Parvovirus B19 (B19V) in the (b) (4) as well as the manufacturing plasma pool.
2. In Section 3.2.S.2.3. Control of Materials (Human Fibrinogen or Human Thrombin), you stated that the (b) (4) manufacturing plasma pools have been tested and found to be non-reactive for viral markers of infection, including B19V.

Please provide the acceptance limits for the level of B19V DNA in the (b) (4) manufacturing pool, and the results of all the plasma pools tested so far based on your quantitative NAT for B19V.

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 26, 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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Center for Biologics Evaluation and Research
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