

From: Do, Yu
To: Joan.robertson@grifols.com
Subject: Pediatric Study: Original BLA, BL 125640/0, Fibrin Sealant (Human), Instituto Grifols, S.A.
Date: Thursday, March 16, 2017 2:00:00 PM
Attachments: [image013.png](#)
Importance: High

Dear Ms. Robertson:

This is our current stance on your pediatric study under review with respect to BL 125640/0:

The deferred pediatric study under consideration would likely be a single study, provided that all three indications are sufficiently evaluated in the study. The protocol must ensure stratification based on the type of surgery, specifying a minimum required number for each procedure (sample size) to allow the Agency an assessment of the safety and hemostatic efficacy for each type of surgery.

The sponsor may submit the study under one of the existing INDs; the choice would be for the IND that has the most prevalent pediatric surgical indication. The clinical reviewer(s) will provide additional comments upon reviewing the protocol.

Please let me know if you have any additional questions. Thanks.

Sincerely,

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