

From: Alicea, Candido  
Sent: Wednesday, August 22, 2018 12:38 PM  
To: 'joan.robertson@grifols.com'  
Cc: Riggins, Patrick; Alicea, Candido  
Subject: Information Request #4: STN 125683/0, Grifols Therapeutics LLC Immune Globulin Subcutaneous (Human), 20%, Action due date July 9, 2019

Our Reference: BL 125683/0

Dear Ms. Robertson:

We are reviewing your July 9, 2018, original biologics license application for Immune Globulin Subcutaneous (Human), 20%. We are requesting that you provide the following information:

1. In the Pediatric Study plan section you reference a non-IND Study GTI1503. The status of the study is unclear. Please advise the number of subjects enrolled to date and whether the study is ongoing or completed. If ongoing, provide the estimated completion date.

Please submit your response to this information request as an amendment to this file by August 23, 2018, referencing the date of this request. If you anticipate you will not be able to respond by this date, please contact me immediately so a new response date can be identified.

The review of this submission is on-going and issues may be added, expanded upon, or modified as we continue to review this submission.

If you have any questions, please contact me at (240) 402-8310.

Sincerely,

Candido

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