

From: Alicea, Candido
Sent: Friday, August 31, 2018 7:22 PM
To: 'joan.robertson@grifols.com'
Cc: Riggins, Patrick
Subject: Information Request #5: 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. Please include all available interim safety data as a 120-day safety update. This should include Study GTI1503, but is not limited to data from this study protocol.
2. Please submit any key revisions to the original protocol and their dates of implementation for non-IND Study GTI1503.
3. Please submit case reports for any serious adverse events (SAEs) that may have occurred within GTI1503 and your assessment as to whether any SAEs are related to the administration of IGSC 20%.

Please submit your response to this information request as an amendment to this file by September 6, 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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