

From: Alicea, Candido
Sent: Friday, August 31, 2018 7:37 PM
To: 'joan.robertson@grifols.com'
Cc: Riggins, Patrick
Subject: Information Request #6 PK: 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 follow-up from information #3:

1. Please provide individual body weight, dose given to individual subjects based on per kg body weight, and total dose in each subject in your PK study (IV and SC) data also for 3-week schedule.

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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