

From: Alicea, Candido  
Sent: Wednesday, May 29, 2019 2:26 PM  
To: joan.robertson@grifols.com  
Subject: RE: Information Request #30: BLA 125683/0, Grifols Therapeutics LLC  
Immune Globulin Subcutaneous (Human), 20%

Our Reference: BLA 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 make the following amendment:

After reviewing your response dated May 1, 2019 regarding the validation report of the analytical procedure (b) (4) [REDACTED] for STN 125683/0, we have the following requests for additional information to continue our review.

- a. Please provide protein concentration of each sample for (b) (4) [REDACTED] in Table 1 (page 1 of your response to our previous IR (Amendment 32)).

(b) (4)

[REDACTED]

(b) (4)

[REDACTED]

Please provide your response by June 6, 2019.

If you feel a clarification is needed for our IR, please contact Dr. Candido Alicea to schedule a teleconference.

Regards,

Candido

Cándido Alicea Ph.D.

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