

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.

CDR, USPHS
Regulatory Project Manager
Consumer Safety Officer
Food and Drug Administration
Center for Biologics Evaluation and Research
Office of Tissues and Advanced Therapies
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Phone: 240-402-8310
Fax: 301-595-1303
candido.alicea@fda.hhs.gov

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