

From: Alicea, Candido
Sent: Wednesday, April 17, 2019 9:53 AM
To: joan.robertson@grifols.com
Subject: Information Request #25: 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 April 5, 2019 regarding the validation report of the analytical procedure (b) (4) for STN 125683/0, we have the following requests for additional information to continue our review.

1. In the response to question No. 3 of FDA IR dated March 22, 2019, (b) (4)
2. (b) (4) Results with such large variation are not acceptable for this method and contradict the precision data in the validation report. Please re-evaluate your results for the linearity plot (b) (4) and submit for review.
3. Please give an example of the calculation for the (b) (4) in Table 2.

The review of this submission is on-going and issues may be added, expanded upon, or modified as we continue to review this submission. Please provide your response by COB May 1, 2019 and submit your response to this information request as an amendment to your BLA referencing the date of this request.

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

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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