

From: Alicea, Candido
Sent: Thursday, February 14, 2019 10:21 AM
To: joan.robertson@grifols.com
Subject: Information Request #17: 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 Dec. 14, 2018 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:

1. Please explain how the (b) (4) [REDACTED] used to generate samples for linearity study in section 5.2.1 of the validation report (Doc # QOAS-2014-116).

2. In your response 2a, the (b) (4) [REDACTED]

3. (b) (4) [REDACTED]
Please reevaluate the linearity of (b) (4) [REDACTED] without this data point and submit for review.

4. We could not accept the (b) (4) [REDACTED]

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 February 28, 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

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