

From: Alicea, Candido
Sent: Friday, March 22, 2019 5:30 PM
To: 'joan.robertson@grifols.com'
Subject: Information Request #22: 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 Feb. 28, 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. Please provide the method used for the determination of

(b) (4) that are used to generate samples for linearity study in section 5.2.1 of the validation report (Doc # QOAS-2014-116).

2. In Figure 6-6 (page 33) of the validation report QOAS-2014-116, (b) (4)

3. The linearity plot you submitted for (b) (4) in amendment 15 (dated Dec.14, 2018) is not acceptable because it uses inappropriate (b) (4).

Please provide the plot of (b) (4) and the results of linear regression analysis of the plot.

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 April 5, 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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