

From: Alicea, Candido
Sent: Monday, March 25, 2019 8:30 PM
To: 'joan.robertson@grifols.com'
Subject: Information Request #24: 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:

1. Please provide a copy of the SOP for “Determination of (b) (4) [REDACTED] According to the (b) (4) [REDACTED] using the (b) (4) [REDACTED] Method”.
2. Please provide the qualification study reports for using the in-house materials as the positive control (b) (4) [REDACTED] in determination of (b) (4) [REDACTED] and as the positive (b) (4) [REDACTED] and negative (b) (4) [REDACTED] controls in determination of (b) (4) [REDACTED]. The reports should include the preparation, storage, and stability monitoring of the in-house controls and adequate calibration of them against the (b) (4) [REDACTED] reference materials, i.e., (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 April 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

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