

From: Alicea, Candido
Sent: Sunday, March 24, 2019 4:28 PM
To: 'joan.robertson@grifols.com'
Subject: Information Request #23: 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 clarify for the Polio Potency specification whether the (b) (4) CBER Reference refers to product that has been (b) (4), and also please update the Polio Potency lot release wording accordingly.

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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