

From: Alicea, Candido
Sent: Friday, March 15, 2019 3:56 PM
To: joan.robertson@grifols.com
Subject: Information Request #20: 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 SOP CS-000-AB-001005, Process Outline for the IGSC 20% Manufacturing Process (b) (4).

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 March 20, 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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