

From: Alicea, Candido
Sent: Monday, August 06, 2018 2:59 PM
To: 'joan.robertson@grifols.com'
Subject: Information Request #1: 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. Amend your list and description of investigators table (located in CTD Module 5 within the folder 5.3.3.2) with the telephone number(s) for each clinical investigator who participated in the study of Protocol GTI1502

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 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.

Sincerely,

Candido

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