

From: Alicea, Candido
Sent: Monday, April 29, 2019 10:22 AM
To: joan.robertson@grifols.com
Subject: Information Request #27: 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. Regarding your response to IR #11 question #3 received on January 3, 2019, please indicate the specific organism(s) that was/were identified from the investigation of Incident #971692.
2. Regarding your (b) (4) study, please describe the worst-case parameters determined from information provided in the questionnaire. Also, explain how these worst-case parameters were used to determine the appropriate conditions used in the scaled-down study such as (b) (4) conditions.

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 May 6, 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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