

From: Alicea, Candido
Sent: Wednesday, August 15, 2018 3:20 PM
To: 'joan.robertson@grifols.com'
Cc: Riggins, Patrick
Subject: Information Request #2: BL 125683/0, Grifols Therapeutics LLC Immune Globulin Subcutaneous (Human), 20%

Our Reference: BL 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 provide the following information:

1. Please provide individual body weight, dose given to individual subjects based on per kg body weight, and total dose in each subject in your PK study (IV and SC) for both 3-week and 4-week schedule.

Please submit your response to this information request as an amendment to this file by August 21, 2018, referencing the date of this request. If you anticipate you will not be able to respond by this date, please contact me immediately so a new response date can be identified.

The review of this submission is on-going and issues may be added, expanded upon, or modified as we continue to review this submission.

If you have any questions, please contact me at (240) 402-8310.

Sincerely,

Candido

Cándido Alicea Ph.D.
CDR, USPHS
Regulatory Project Manager
Center for Biologics Evaluation and Research
Office of Tissues and Advanced Therapies
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Phone: 240-402-8310
Fax: 301-595-1303
candido.alicea@fda.hhs.gov

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