

From: Alicea, Candido
Sent: Wednesday, August 22, 2018 12:38 PM
To: 'joan.robertson@grifols.com'
Cc: Riggins, Patrick; Alicea, Candido
Subject: Information Request #4: STN 125683/0, Grifols Therapeutics LLC Immune Globulin Subcutaneous (Human), 20%, Action due date July 9, 2019

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. In the Pediatric Study plan section you reference a non-IND Study GTI1503. The status of the study is unclear. Please advise the number of subjects enrolled to date and whether the study is ongoing or completed. If ongoing, provide the estimated completion date.

Please submit your response to this information request as an amendment to this file by August 23, 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

"THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have

received this
document in error, please immediately notify the sender by e-mail or phone."