

From: Alicea, Candido
Sent: Wednesday, February 06, 2019 1:50 PM
To: 'joan.robertson@grifols.com'
Subject: Information Request #16: 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:

Sterility Test

1. For the control of IGSC, 20%, please provide the qualification report for the sterility test showing the test was qualified in accordance with (b) (4) to confirm the product matrix for the final container drug product is suitable for the intended test method. Please include the indicator microorganisms and environmental isolates tested, their initial inoculum CFU count and media assignment, conformance lot numbers, and incubation conditions used in the qualification.

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 February 22, 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

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."