

From: Alicea, Candido
Sent: Wednesday, May 22, 2019 2:31 PM
To: Robertson, Joan; Smith, Kelly
Subject: Information Request #29: 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 determined that the following information is necessary to continue our review:

1. With regards to your method SOP, CS-000-BF-034, "Poliomyelitis and Measles Neutralization Test (b) (4)": we noticed that the method SOP version you submitted to this Original BLA file still mentions the use of poliovirus Type (b) (4) (version 24.0, effective 25-SEP-2017). You have already (b) (4) poliovirus Type (b) (4) for testing your IGIV-C 10% product (STN 125046/1545, submitted 13-NOV-2017, approved 15-MAR-2018), therefore this should also apply to your IGSC 20% product.

a. Please provide the most recent version of your method SOP, CS-000-BF-034, which should not contain any mention of poliovirus Type (b) (4)

b. Please confirm that your Polio Potency specification is for testing anti-poliovirus Type (b) (4) antibodies only.

Please submit your response to this information request as an amendment to this file by May 30, 2019, 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.

Regards,

Candido

Cándido Alicea Ph.D.
CDR, USPHS
Regulatory Project Manager
Consumer Safety Officer
Food and Drug Administration
Center for Biologics Evaluation and Research
Office of Tissues and Advanced Therapies
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."