

From: Alicea, Candido
Sent: Wednesday, March 13, 2019 12:44 PM
To: 'joan.robertson@grifols.com'
Subject: RE: Information Request #18: STN 125683/0, Immune Globulin Subcutaneous (Human), Action due date July 9, 2019

Our Reference: BLA 125683/0

Dear Ms. Robertson:

We are reviewing your July 9, 2018, biologics license application for Immune Globulin Subcutaneous (Human) 20%. We determined that the following information is necessary to continue our review:

Environmental isolate Test and use of (b) (4) standard.

1. In your response to IR (i.e., Amendment 125683/0.23), received 22 February of 2019, you indicated that environmental testing is routinely performed on adequacy testing for (b) (4) and will be performed for (b) (4) with a target implementation date of Q3 2019.

However, CBER is requesting the testing of known environmental isolates (EI) as part of your sterility test qualification process, as the (b) (4) indicator microorganisms are only a general representation of test suitability, where the testing of your known EI will provide sterility assurance specific to the product, your facility and indicated test method. Please submit the requested sterility qualification report by April 26, 2019. If the report is not available by this time, please provide the time frame by which the qualification will be complete.

2. CBER's U.S. Standard Diphtheria Antitoxin is calibrated using the (b) (4) neutralization assay, not a (b) (4) neutralization assay. Therefore, CBER recommends you re-qualify your assay in the near future using the (b) (4) standard (i.e., Diphtheria Antitoxin Human IgG (b) (4) for use in Diphtheria (b) (4) Potency Assay, to prevent future issues associated with using a standard not developed for a more sensitive (b) (4) assay. Please comment.

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 submit your response to this information request as an amendment to this file by April 26, 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

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