

From: Alicea, Candido
Sent: Thursday, March 14, 2019 4:19 PM
To: joan.robertson@grifols.com
Subject: Information Request #19: STN 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:

Comments on LRP templates submitted to BLA 125683/0.4 on 21 August 2018

We recommend the following modifications to the Lot Release protocol template:

1. On page 2 of 3, please add 2 columns to the “Final Container Test Results” table; one for specifications and one for test date. The specification for each test should be stated in the specifications column.
2. On page 2 of 3, please include the specification, test date and result as discussed in the teleconference on 1st October 2018, for (b) (4), osmolality, (b) (4) and revision of the appearance specification.
3. On page 3 of 3, please include spaces for:
 - a. Sterility test specifications and results
 - b. and Pyrogen test specification and results (e.g., Pass or Fail).

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 March 27, 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.
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