

From: Alicea, Candido
Sent: Thursday, September 13, 2018 11:05 PM
To: 'joan.robertson@grifols.com'
Cc: Riggins, Patrick
Subject: Information Request #7 PK: STN 125683/0,Grifols Therapeutics LLC
Immune Globulin Subcutaneous (Human), 20%, Action due date July 9,
2019

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. Regarding your extractables and leachables evaluation for IGSC, 20%, please provide primary reports BA-RTEC-000080, BA-RTEC-000039, BA-RTEC-000040, BA-RTEC-000044, and PRD-18-106 PRD-18-106 or indicate where these may be found in the submission.

Please submit your response to this information request as an amendment to this file by September 20, 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

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