

From: Alicea, Candido
Sent: Friday, October 19, 2018 8:59 PM
To: 'Robertson, Joan'
Subject: Information Request #8 PK: STN 125683/0, Grifols Therapeutics LLC
Immune Globulin Subcutaneous (Human), 20%, Action due date July 9, 2019

Our Reference: BL 125683/0

Dear Ms. Robertson:

We are reviewing your July 9, 2018, supplement to your biologics license application for Immune Globulin Subcutaneous (Human), 20%. We are requesting that you provide the following information:

Sample and Reagent IR for 125683/0

1. Please provide the following conformance lots of Immune Globulin Subcutaneous (Human) (IGSC), 20%, drug product:

- a. (b) (4) 3 vials
- b. (b) (4) 3 vials
- c. (b) (4) 3 vials

2. Please provide the most recent test results with the date of the test for each lot sent.

The samples and reagents should be shipped to:

Alfred Del-Grosso
Food and Drug Administration
Center for Biological Evaluation and Research
Division of Biological Standards and Quality Control
10903 New Hampshire Avenue
WO75, G-656
Silver Spring, MD 20993-0002

Contact Varsha Garnepudi at 240-402-9547 and/or Al-Del-Grosso at 240-402-9470 for questions on the shipment.

We request that requested samples and documentation be sent by November 5, 2018 or notify CBER by then when the shipment can be expected.

The review of this submission is on-going and issues may be added, expanded upon, or modified as we continue to review this submission.

Warm regards,
Candido

Cándido Alicea Ph.D.
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Office of Tissues and Advanced Therapies

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