

From: Alicea, Candido
Sent: Tuesday, March 19, 2019 1:51 PM
To: joan.robertson@grifols.com
Subject: Information Request #21: 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 are requesting that you make the following amendment:

- 1) Please update product specifications to include modifications you sent on November 2, 2018.
- 2) Please include 3.2.P.5.2 to include methods for osmolality, (b) (4)
- 3) Please update CS-000-BB-057 "Product Appearance Test Record" to reflect the updated product appearance language.
- 4) Please update 3.2.P.8 Stability Protocol to reflect the modifications to test acceptance criteria.
- 5) Please commit to providing updated stability information for (b) (4) IGSC 20% process validation batches (study GTI_SR-000106) and (b) (4) IGSC 20% lead commercial batches (study GTI_SR-000107) annually as a product correspondence labelled as a "Postmarketing Submission – Status Update", and to providing a "Postmarketing Submission – Final Study Report" covering these batches no later than Feb. 28, 2020.

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 provide your response by COB March 26, 2019 and submit your response to this information request as an amendment to your BLA referencing the date of this request.

If you have any questions, please contact me at (240) 402-8310.

Regards,

Candido

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