

From: Alicea, Candido
Sent: Saturday, June 01, 2019 10:19 PM
To: joan.robertson@grifols.com
Subject: Information Request #31: 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. Thank you for your responses to IR #26 regarding dosing and administration. We recognize your efforts; however, it will not be possible to label the product based on modeling. We do not have safety information related to the variable dosing regimens proposed from the modeling study and therefore only the dosing from the clinical trial is acceptable.
2. With regard to local infusion site reactions, please provide information about the duration of erythema following infusion. For example, is the erythema noted only at the start of administration or does it last several hours or days following administration of XEMBIFY?

Thank you for responding by 6 June 2019.

Regards,

Candido

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