

From: Alicea, Candido
Sent: Monday, June 17, 2019 12:39 PM
To: Robertson, Joan
Subject: Information Request: STN 125683/0 Immune Globulin Subcutaneous (Human), 20% due date July 9, 2019
Attachments: XEMBIFY LR 125683 0.pdf; Final revision 6-17-2019 draft-labeling-text._dsb.docx

Our Reference: BL 125683/0

Dear Ms. Robertson:

We are reviewing your July 9, 2018, biologics license application for XEMBIFY. We are providing comments to your attached package insert label. Please review and address our comments by agreeing to the edits or providing additional information to these. 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/comments as an amendment to this file by June 20, 2019, referencing the date of this request. Please include both a red-line strike out and clean copy of the revised package insert in WORD format. 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

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