

From: Alicea, Candido
Sent: Wednesday, July 03, 2019 2:00 PM
To: Robertson, Joan
Subject: Final Revision of PI Label for Grifols BLA 125683/0 XEMBIFY
Attachments: annotated-draft-labeling-text.docx

Dear Ms. Robertson,

Attached you will find the FDA's most recent edits to your Package Insert label for BLA 125683/0 XEMBIFY. Please include both a red-line strike out and clean copy of the revised package insert in WORD format. Please respond as soon as possible.

Regards,

Candido

Cándido Alicea Ph.D.
CDR, USPHS
Regulatory Project Manager
Consumer Safety Officer
Food and Drug Administration
Center for Biologics Evaluation and Research
Office of Tissues and Advanced Therapies
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Phone: 240-402-8310
Fax: 301-595-1303
candido.alicea@fda.hhs.gov

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