

From: Alicea, Candido
Sent: Monday, November 19, 2018 12:26 PM
To: 'Robertson, Joan'
Subject: Information Request #9: STN 125683/0, Grifols Therapeutics LLC Immune Globulin Subcutaneous (Human) (b) (4), Action due date July 8, 2019

Our Reference: BL 125683/0

Dear Ms. Robertson:

We are reviewing your July 9, 2018, biologics license application for Immune Globulin Subcutaneous (Human) (b) (4). We determined that the following information is necessary to continue our review:

1. APLB needs a mock up labeling for now (b) (4) (previously (b) (4)). The name is different enough that we need to review the labeling in print.
2. The carton labeling do not have an Expiration Date and Lot # printed on them. Also, the vial labeling do not have the phrase, "Rx only" printed on them. Please have this in mind when providing the new labeling print.

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 as an amendment to this file by COB November 28, 2018, referencing the date of this request. 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. Please acknowledge receipt of the email.

The action due date for this file is July 8, 2019.

Best regards,
Candido

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

"THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not

the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone."