

From: Riggins, Patrick
To: ["maguilera@vcel.com"](mailto:maguilera@vcel.com)
Cc: [Gildner, Jean](#)
Subject: STN 125603 483 Responses
Date: Wednesday, August 31, 2016 9:15:00 AM

APPROVED
By Patrick S. Riggins at 9:18 am, Aug 31, 2016

Margarita,

I am sorry for any confusion regarding where to submit the 483 responses for items that are not normally included in the BLA. As we had previously informed you, they do indeed need to be submitted to the BLA as amendments. They should be included in Module 1, specifically under section 1.11 information amendment: information not covered under Modules 2-5. Just be sure to label them as responses to 483 observations. If you have any further questions about this, do not hesitate to let me know.

Regards,

Pat Riggins

Patrick S. Riggins, Ph.D.
Branch Chief
Regulatory Management Staff
Office of Cellular, Tissue, and Gene Therapies
Center for Biologics Evaluation and Research
Food and Drug Administration
Bldg 71/Room 5236
10903 New Hampshire Avenue
Silver Spring, MD 20993
Phone: (240)402-8346
Fax: (301)595-1303

"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 notify the sender immediately by e-mail or phone."