

From: Alicea, Candido
To: "jennifer.wellman@sparktx.com"; "Paul Gil"
Cc: Morris, Nevitt; Glen, Jacqueline
Subject: Request for Information for BLA 125610
Date: Friday, August 18, 2017 12:28:28 PM
Attachments: image001.png

(File Attachment comment)
Dear Jennifer and Paul,

I am covering for Mr. Nevitt Morris while he is out of the office. The CMC reviewer has asked me to relay this information request to you with an expected response by noon of Aug 23, 2017. In addition to responding to this email remember to submit your responses to your BLA. Please acknowledge receipt of this email.

CMC IR

1.
Please provide Original signed COA for the HEK293 MCB provided by the vendor. If this information is not available, provide a record of verification for each test result.

2.
In your submission Module 3, "3.2.P.3.5 Process Validation and/or Evaluation - Diluent", under the "Table 3 - Additional PPQ Sampling", you stated "Data not reported due to an invalid assay" for the test of "Concentration of Pluronic". Please clarify.

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."
(Unsigned signature field (Click to sign)) Signature field is unsigned