

From: Morris, Nevitt
To: paul.gil@sparktx.com; jim.wang@sparktx.com
Cc: Morris, Nevitt
Subject: BLA 125610 CMC Information Request 11.29.17
Date: Wednesday, November 29, 2017 4:23:57 PM
Attachments: image001.png

(File Attachment comment)
Hi Paul and Jim:

Please see the CMC Information Request below. We are asking for a response by close of business, tomorrow, November 30, 2017.

We note that the BLA submission (eCTD) has not been updated entirely for all tests and specifications for release of Drug Substance (3.2.S.4.1), and Drug Product (3.2.P.5.1), in the submission to reflect the changes agreed upon. Specifically, please update the BLA to reflect the following changes:

a.

Drug Substance (3.2.S.4.1):

i. (b) (4) [please refer to Response to FDA Request for Information on 21 November 2017, Spark response 1.a.(1)]

ii. (b) (4) (please refer to Response to FDA Request for Information - 15 September 2017, Under 1.4; we agree to your proposal to (b) (4) .

iii. (b) (4) [Please refer to Response to FDA Request for Information on 21 November 2017, Spark response 1.b]

b.

Drug Product (3.2.P.5.1)

In Vitro Relative Potency of (b) (4) by (b) (4) Assay (b) (4) ; please revise from (b) (4) to (b) (4) [please refer to Response to FDA Request for Information on 21 November 2017, Spark response 1.a.(1)]

c.

Accordingly please update all the stability plans to the revised acceptance criteria for pH (b) (4) , (b) (4) , in vitro relative potency of (b) (4) by (b) (4) assay (b) (4) , and in vitro relative potency of (b) (4) assay (b) (4) .
Please acknowledge receipt of this email.

Thanks

Nevitt

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

Nevitt Morris

Nevitt
Morris,
RN,
BSN,
BS
Consumer
Safety
Officer
Office
of
Tissues
and
Advanced
Therapies
Center
for
Biologics
Evaluation
and
Research
(CBER)

U.S.
Food
and
Drug
Administration
Building
71,
Room
4207
10903
New
Hampshire
Avenue
Silver
Spring,
MD 20993
Phone: (240)
402-8269
Fax: (301)
595-1303
Nevitt.Morris@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 immediately by e-mail or phone.