

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

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