

From:
Morris, Nevitt

To:
Jim Wang

Cc:
paul.gil@sparktx.com; Morris, Nevitt

Subject:
RE: BLA 12610 Spark Information Request F/U DBSQC 10/23/17

Date:
Monday, October 23, 2017 5:14:43 PM

Attachments:
image001.png
image002.png

(File Attachment comment)
(File Attachment comment)
Hi Jim and Paul:

Please disregard the previous Information Request I sent our earlier today. This one is the correct IR. Please acknowledge receipt and provide a response within one week, by October 30, 2017:

In regards to Spark Therapeutics Response to FDA's initial information request send on October 4th, 2017 for (b) (4), document "Validation Report - TS102062GMP.R02" provided the procedure of the (b) (4) but did not include test results. CBER requests that you submit the (b) (4)

method qualification assay results with conformance bath numbers for the drug substance to show the test samples meet their qualification acceptance criteria according to (b) (4) or (b) (4).

Thanks and our apologies for any confusion.

Nevitt

Nevitt Morris

Nevitt
Morris,
RN,
BSN,

BS
Consumer
Safety
Officer
Office
of
Tissues
and
Advanced
Therapies
Center
for
Biologics
Evaluation
and
Research
(CBER)

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and
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Phone: (240)
402-8269
Fax: (301)
595-1303
Nevitt.Morris@fda.hhs.gov

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From:
Jim
Wang
[mailto:jim.wang@sparktx.com]
Sent:
Monday,
October
23,
2017
4:45
PM
To:
Morris,
Nevitt
<Nevitt.Morris@fda.hhs.gov>
Subject:
RE:
BLA
12610
Spark
Information
Request
F/U
DBSQC
10/23/17

Hi
Nevitt,

It
appears
that
both
of
them
are
out
of
the

office. I
acknowledge
the
receipt
of
the
information
request
and
have
forwarded
to
the
CMC
team.

Best
Regards,

Jim

From:
Morris,
Nevitt
[mailto:Nevitt.Morris@fda.hhs.gov]
Sent:
Monday,
October
23,
2017
1:44
PM
To:
Mike
Ferenz
<Mike.Ferenz@sparktx.com>
Cc:
Jim
Wang
<jim.wang@sparktx.com>;
Morris,
Nevitt
<Nevitt.Morris@fda.hhs.gov>
Subject:
FW:
BLA
12610
Spark
Information
Request
F/U

DBSQC
10/23/17
Importance:
High

Hi
Mike:

I
am
just
forwarding
the
Information
Request
to
you
since
Paul
Gil
is
out
of
the
office.

Thanks

Nevitt

Nevitt Morris

Nevitt
Morris,
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BSN,
BS
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From:
Morris,
Nevitt
Sent:
Monday,
October
23,
2017
1:41
PM
To:
paul.gil@sparktx.com
Cc:
Morris,
Nevitt
<Nevitt.Morris@fda.hhs.gov>;
jim.wang@sparktx.com
Subject:
BLA
12610
Spark
Information
Request
F/U
DBSQC
10/23/17
Importance:
High

Hi Paul and Jim:

In regards to Spark Therapeutics Response to FDA's initial information request send on October 4th, 2017 for (b) (4) , document "Validation Report - TS102062GMP.R02" provided the procedure of the (b) (4) but did not include test results. CBER requests that you submit the (b) (4) method qualification assay results for the drug substance to show the test samples meet their qualification acceptance criteria according to (b) (4) . Please provide the conformance batch numbers, (b) (4) test results data used in the study.

Please provide a response to the above Information Request by Monday, October 30, 2017 and please acknowledged receipt of the email Information Request.

Thanks

Nevitt

Nevitt Morris

Nevitt
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RN,
BSN,
BS
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Safety
Officer

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and
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