

From: Morris, Nevitt
To: paul.gil@sparktx.com; jim.wang@sparktx.com
Cc: Morris, Nevitt
Subject: RE: BLA 125610 Response to IR of 24Nov2017
Date: Wednesday, November 29, 2017 4:46:34 PM
Attachments: image002.png

20170907_Information Request for BLA 125610.docx
image004.png

(File Attachment comment)

(File Attachment comment)

(File Attachment comment)

Hi Paul:

The DBSQC Reviewer had the following comments. Please refer to the attached document regarding this Information Request to the LRP.

Information Request for BLA 125610, LRP:

1) In section N on page 2 of 3, please change the endotoxin units from EU/mL to IU/mL.

2) Please add Endotoxin detailed results using the CBER (b) (4) template attached in this email.

3) Please add Sterility detailed results using the CBER sterility template included in this email.

Could you provide a response by Thursday, November 30, 2017 close of business.

Please acknowledge receipt of this email request.

Thanks

Nevitt

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
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10903
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Phone: (240)
402-8269
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595-1303
Nevitt.Morris@fda.hhs.gov

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

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From: Paul
Gil
[mailto:Paul.gil@sparktx.com]
Sent: Wednesday,
November
29,
2017
11:09
AM
To: Morris,
Nevitt
<Nevitt.Morris@fda.hhs.gov>
Subject: BLA
125610
Response
to
IR
of
24Nov2017

Hi
Nevitt,
This
should
be
coming
through
the

gateway
tomorrow.
The
LRP
is
attached
for
the
review
team.
Regards,
Paul

From: Paul
Gil
Sent: Monday,
November
27,
2017
12:48
PM
To: 'Morris,
Nevitt'
<Nevitt.Morris@fda.hhs.gov>
Cc: Bi,
Lilia
Lei
<LiliaLei.Bi@fda.hhs.gov>
Subject: BLA
125610
Response
to
IR
of
30Nov2017

Hi
Nevitt,

Thank
you
for
your
Information
Request
received
24
November
2017.
Attached
please

find
a
.pdf
file
of
1.1.1
containing
our
response.
The
hyperlink
will
be
live
when
the
response
is
submitted
through
the
ESG
on
Thursday,
November
30,
2017
(Sequence
0050).
The
LRP
is
attached
for
the
reviewers.

Please
acknowledge
receipt
of
this
email.

Regards,
Paul

Paul J. Gil, Ph.D.

Regulatory
CMC

Lead

paul.gil@sparktx.com

3737
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