

From: [Agnihothram, Sudhakar](#)
To: [Michelle Olsen](#)
Cc: [Paul Dawidczyk](#); [Resnick, Josephine](#); [Kulinski, Joseph](#)
Subject: RE: [EXTERNAL] BLA 125752 IR #7
Date: Thursday, October 14, 2021 8:55:00 PM

Sudhakar S. Agnihothram - S Send this message to a friend or colleague. To help protect your privacy, Outlook prevented automatic download of some pictures from the Internet.

Thanks, Michelle.

In your letter of cross reference to the ACC's master file, please specify the amendment number, date of submission and name of the files that contain the information relevant to items 3 and 7 from IR #7.

Thanks,
Sudhakar

Sudhakar Agnihothram, B.Pharm., Ph.D
Biologist (Primary Reviewer)
Center for Biologics Evaluation and Research
Office of Vaccines Research and Review
U.S. Food and Drug Administration
Tel: 301-348-3056 (Off)
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Fax: 301-827-3532
Email: Sudhakar.Agnihothram@fda.hhs.gov

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-----Original Message-----

From: Michelle Olsen <Michelle.Olsen@modernatx.com>
Sent: Thursday, October 14, 2021 8:35 PM
To: Agnihothram, Sudhakar <Sudhakar.Agnihothram@fda.hhs.gov>
Cc: Paul Dawidczyk <(b) (6) @modernatx.com>; Resnick, Josephine <Josephine.Resnick@fda.hhs.gov>; Kulinski, Joseph <Joseph.Kulinski@fda.hhs.gov>
Subject: Re: [EXTERNAL] BLA 125752 IR #7

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Dear Sudhakar,

I just spoke with Paul regarding IR#7 items 3 and 7. With regards to the endotoxin testing through Cape Cod Associates, we are working with them to submit as soon as possible (tomorrow or Monday at the latest). We will submit a letter of cross reference to their file.

Best regards,
Michelle

Sent from my iPhone

> On Oct 12, 2021, at 9:13 PM, Agnihothram, Sudhakar <Sudhakar.Agnihothram@fda.hhs.gov> wrote:

>

> EXTERNAL

>

> Thanks, Paul.

>

> Please make sure to include Dr. Josephine Resnick and Dr. Joseph Kulinski in all communications related to the STN 125752.

>

> Thanks,

> Sudhakar

>

> Sudhakar Agnihothram, B.Pharm., Ph.D

> Biologist (Primary Reviewer)

> Center for Biologics Evaluation and Research Office of Vaccines

> Research and Review U.S. Food and Drug Administration

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>

> From: Paul Dawidczyk <(b) (6) @modernatx.com>

> Sent: Tuesday, October 12, 2021 9:04 PM

> To: Agnihothram, Sudhakar <Sudhakar.Agnihothram@fda.hhs.gov>

> Cc: Michelle Olsen <Michelle.Olsen@modernatx.com>

> Subject: [EXTERNAL] BLA 125752 IR #7

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> Hello Sudhakar:

>

> I have attached the draft response for BLA 125752 IR #7. We unfortunately missed our publishing window to submit through the eGateway tonight and I wanted to make sure that this was submitted per the response due date.

Please acknowledge receipt.

>

> Regards,

> Paul

>

> Paul Dawidczyk

> VP, Regulatory Affairs CMC | Moderna

> mobile (b) (6) |

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