

From: [Michelle Olsen](#)
To: [Resnick, Josephine](#)
Cc: [Agnihothram, Sudhakar](#); [Kulinski, Joseph](#); [Carla Vinals](#); [Charbel Haber](#)
Subject: [EXTERNAL] RE: Midcycle Communication Meeting
Date: Wednesday, November 24, 2021 12:32:56 PM
Attachments: [image002.png](#)

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Dear Jo,

We agree to cancel the meeting for the mid-cycle review based on the progress of the review. We also do not have any issues, additional data, or analyses for this application to discuss.

Best regards,
Michelle

Michelle Olsen, PhD

Associate Director, Regulatory Strategy – Infectious Diseases | Moderna
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From: Resnick, Josephine <Josephine.Resnick@fda.hhs.gov>
Sent: Tuesday, November 23, 2021 3:01 PM
To: Michelle Olsen <Michelle.Olsen@modernatx.com>
Cc: Agnihothram, Sudhakar <Sudhakar.Agnihothram@fda.hhs.gov>; Kulinski, Joseph <Joseph.Kulinski@fda.hhs.gov>
Subject: Midcycle Communication Meeting

EXTERNAL

Dear Michelle,

Around the midcycle point of the review cycle, CBER offers the opportunity to discuss the status of the review via a Midcycle communication meeting. As we are approaching that general timeframe, we wanted to check in with you regarding this.

Based on the progress of the review, we do not have any substantive review issues to discuss at this time. If you do not have any issues, additional data, or analyses for this application to discuss, the Midcycle communication meeting can be cancelled.

Please inform us in writing as soon as possible if you agree and would like to cancel this meeting.

Please let me know if you have any questions.

Warm regards,

Jo

Josephine Resnick, Ph.D

Biologist (Primary Reviewer)

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