

From: Michael Schwartz <michael.p.schwartz@gsk.com>

Sent: Wednesday, March 2, 2022 9:10 AM

To: Clifford, Julianne <Julianne.Clifford@fda.hhs.gov>; Vujcic, Luba <Luba.Vujcic@fda.hhs.gov>; Sharma, Nikunj <Nikunj.Sharma@fda.hhs.gov>

Subject: [EXTERNAL] RE: BLA STN 125748 --- Late Cycle Meeting Materials

Hi Juli, Luba and Nikunj,

Thank you for the meeting material and agenda for the late cycle review meeting. The status of the BLA review is very clear from the provided meeting materials and there appear to be no major issues identified by FDA at this time. Regarding agenda item #7, we have no questions for FDA or concerns to discuss with FDA at this time. Thus, GSK is OK to cancel the teleconference scheduled for tomorrow, if FDA agrees.

Please confirm.

Thank you,

Mike

From: Clifford, Julianne <Julianne.Clifford@fda.hhs.gov>

Sent: Friday, February 25, 2022 5:12 PM

To: Michael Schwartz <michael.p.schwartz@gsk.com>; USMMR Regulatory <USMMR.Regulatory@gsk.com>

Cc: Vujcic, Luba <Luba.Vujcic@fda.hhs.gov>; Sharma, Nikunj <Nikunj.Sharma@fda.hhs.gov>

Subject: BLA STN 125748 --- Late Cycle Meeting Materials

Importance: High

EXTERNAL

Dear Mr. Schwartz,

We refer you to your BLA submission STN 125748 for Measles, Mumps and Rubella Virus Vaccine, Live, submitted June 4, 2021. Attached please find the Late Cycle Meeting Materials communication which includes the agenda for our meeting scheduled for March 3, 2022, at 10:30 AM.

I am including the call-in conferencing numbers below for participants located in the US and Belgium, but please do not hesitate to let me know if you require numbers for participants from additional locations.

Join by Telephone

For higher quality, dial a number based on your current location.

Dial:

US: +1 669 254 5252 or +1 646 828 7666 or +1 551 285 1373 or +1 669 216 1590
or 833 568 8864 (Toll Free)

Meeting ID: (b) (4)

Passcode: (b) (4)

Belgium	(b) (4)	
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Please reply to confirm receipt of this email. Please do not hesitate to contact me if you have any questions.

Sincerely,

Juli Clifford

Julianne C. M. Clifford, Ph.D.

Biologist

Center for Biologics Evaluation & Research
Office of Vaccines Research and Review
U.S. Food and Drug Administration
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