



Our STN: BL 125768/0

MID-CYCLE COMMUNICATION

April 19, 2023

Pfizer Inc.
Attention: Nirvana Moodley
500 Arcola Road
Collegeville, PA 19426

Dear Ms. Moodley:

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 questions, additional data, or analyses to discuss for this application, the Mid-Cycle meeting may be cancelled upon your request. Please inform us in writing within two business days if you would like to cancel this meeting. If not, please identify your topics for discussion at the Mid-Cycle meeting.

Please include a reference to STN 125768/0 in your future submissions related to Respiratory Syncytial Virus Vaccine.

If you have any questions, please contact the Regulatory Project Managers, Paul Keller, Ph.D. (Paul.Keller@fda.hhs.gov), Ms. Laura Montague (Laura.Montague@fda.hhs.gov), and Vera Stupina, Ph.D. (Vera.Stupina@fda.hhs.gov).

Sincerely,

Loris McVittie, Ph.D.
Deputy Director - Regulatory
Division of Viral and
Related Products Applications
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research