



Our STN: BL 125769/0

MID-CYCLE COMMUNICATION

January 17, 2023

Pfizer Inc.
Attention: Rebecca Klein, Ph.D.
500 Arcola Road
Collegeville, PA 19426

Dear Dr. Klein:

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 125769/0 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
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Evaluation and Research