LATE-CYCLE MEETING MATERIALS

Our STN: BL 125769/0

April 06, 2023

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

Dear Dr. Klein:

Please refer to your Biologic License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Respiratory Syncytial Virus Vaccine, (ABRYSVO) for intramuscular injection.

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 Late 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 Late Cycle meeting.

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
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Related Products Applications
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