



Our Reference: EUA 27034

**EUA AMENDMENT –
CONCURRENCE** August 22, 2021

Pfizer Inc.
Attention: Neda Aghajani Memar
500 Arcola Road
Collegeville, PA 19426

Dear Dr. Aghajani Memar:

Please refer to your Emergency Use Authorization (EUA) for emergency use of Pfizer COVID-19 Vaccine, re-issued on August 12, 2021, under section 564 of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 360bbb-3).

We also refer you to your EUA amendment 260 submitted and received on August 13, 2021.

In summary, your amendment provides information and data to support the extension of shelf-life of Pfizer-BioNTech COVID-19 Vaccine stored at -90° to -60°C from 6 months to 9 months. We confirm that the concurrence on extending the shelf-life from 6 months to 9 months when stored at -90° to -60°C is also applicable to batches that might have expired prior to the issuance of this concurrence letter provided they have been stored at -90° to -60°C .

We have completed our review and based on the information submitted, we concur with this change. We remind you that any changes that you plan to implement to the description of the product, manufacturing process, facilities, or equipment will need to be submitted as an amendment to the EUA and not implemented without concurrence by the Agency.

If you have any questions, please contact the Regulatory Project Manager, Ramachandra Naik, Ph.D., at 301-796-2640.

Sincerely,

Marion Gruber, PhD
Director
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research