Our Reference: EUA 27034

EUA AMENDMENT – CONCURRENCE
November 15, 2023

Pfizer Inc.
Attention: Leslie Sands
66 Hudson Boulevard East
New York, NY, 10001

Dear Ms. Sands:

Please refer to your Emergency Use Authorization (EUA) for emergency use of Pfizer-BioNTech COVID-19 Vaccine, re-issued on September 11, 2023, under section 564 of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 360bbb-3).

We also refer to your EUA amendment 784 submitted and received on November 3, 2023.

In summary, your amendment describes the following change:

- Extension of the expiry dating period for the 0.033 mg/mL BNT162b2 Tris/Sucrose drug product (supplied in either single-dose vials or multi-dose vials) from 12 months to 18 months when stored between -90ºC to -60ºC (-130ºF to -76ºF).

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 Managers, Meghan Maguire Thon, Ph.D. (at Meghan.MaguireThon@fda.hhs.gov), CAPT Michael Smith, Ph.D. (at Michael.Smith2@fda.hhs.gov) and Julianne Clifford, Ph.D. (at Julianne.Clifford@fda.hhs.gov), or at 301-796-2640.

Sincerely,

David C. Kaslow, M.D.
Director
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research

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