July 14, 2023

Pfizer Inc.
Attention: Leslie Sands
500 Arcola Road
Collegeville, PA 19426

Dear Ms. Sands:

Please refer to your Emergency Use Authorization (EUA) for emergency use of Pfizer-BioNTech COVID-19 Vaccine, re-issued on April 28, 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 748 submitted and received on June 29, 2023.

In summary, your amendment describes the following change:

- Extension of the expiry dating period for the 30-mcg PBS/Sucrose drug product (supplied in multiple dose vials) from 18 months to 24 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

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov