



May 19, 2021

Pfizer Inc.
Attention: Ms. Elisa Harkins
500 Arcola Road
Collegeville, PA 19426

Re: EUA 27034 - Emergency Use Authorization of Pfizer-BioNTech COVID-19 Vaccine, Reissued on May 10, 2021, Under Section 564 of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 360bbb-3); Requests in Multiple Amendments April 30, 2021 – May 18, 2021 to Update the Authorized Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) - (including Full EUA Prescribing Information)

Dear Ms. Harkins:

This letter is to notify you that we have reviewed the requested changes and data to support the revisions to your Authorized Full EUA Prescribing Information and that your request is granted.

2.1 Preparation for Administration
THAWING PRIOR TO DILUTION

-thawed vials can be stored in the refrigerator for up to 1 month.

19 How Supplied/Storage and Handling

Thawed Vials Before Dilution

Thawed Under Refrigeration

- Thaw and then store undiluted vials in the refrigerator [2°C to 8°C (35°F to 46°F)] for up to 1 month.

These changes were also made to the EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) (short version) for consistency.

By submitting these amendments for review and concurrence by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the May 10, 2021 letter authorizing the emergency use of Pfizer-BioNTech COVID-19 Vaccine.

Sincerely,

--/S/--

Marion Gruber, Ph.D.
Director
Office of Vaccines Research and Review

