



July 14, 2023

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

Re: EUA 27034 - Emergency Use Authorization of Pfizer-BioNTech COVID-19 Vaccine, Reissued on April 28, 2023, under Section 564 of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 360bbb-3); Request in Amendment submitted and received on June 30, 2023, to Update the Authorized Fact Sheet for Healthcare Providers Administering Vaccine: Emergency Use Authorization of Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5)

Dear Ms. Sands:

This letter is to notify you that we have reviewed the requested changes and data to support the revisions to your Authorized Fact Sheet and that your request is granted.

We concur with your request for an extension of the expiry dating period for the 30-, 10-, and 3-mcg Tris/Sucrose drug products (supplied in multiple dose vials) and the 30-mcg Tris/Sucrose drug product (supplied in single dose vials) from 18 months to 24 months when stored between -90°C to -60°C (-130°F to -76°F) in section 16 of the Fact Sheet for Healthcare Providers Administering Vaccine: Emergency Use Authorization of Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) as indicated below:

16 HOW SUPPLIED/STORAGE AND HANDLING

Frozen Vials Prior to Use

Alternatively, frozen vials may be stored in an ultra-low temperature freezer at -90°C to -60°C (-130°F to -76°F) for up to 24 months from the date of manufacture. Do not store vials at -25°C to -15°C (-13°F to 5°F). Once vials are thawed, they should not be refrozen.

By submitting this amendment for review and concurrence by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the April 28, 2023 letter authorizing the emergency use of Pfizer-BioNTech COVID-19 Vaccine.

Sincerely,

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