DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

January 27, 2021

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

Re: EUA 27034/50 - Requests for Amendments to Update the Authorized Health Care Provider Fact Sheet – EUA Full Prescribing Information
Product Name: Pfizer-BioNTech COVID-19 Vaccine
Dated: January 15, 2021
Received: January 15, 2021

Dear Ms. Harkins:

We refer to our Emergency Use Authorization Amendment Granting letter dated January 22, 2021, which contained the following error:

The temperature range was incorrectly described in the section headed *Transportation at 2°C to 8°C (35°F to 46°F)*, and referenced -96°C instead of -90°C. The letter has been corrected to say that if local redistribution is needed and full cartons containing vials cannot be transported at -90°C to -60°C (-130°F to -76°F), available data support transportation of one or more thawed vials at 2°C to 8°C (35°F to 46°F) for up to 12 hours.

This replacement letter incorporates the correction of the error. The effective date will remain January 22, 2021, the date of the original Emergency Use Authorization Amendment Granting letter.

This letter is to notify you that your request to update the EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) – EUA Full Prescribing Information to include (1) modifications in acceptable storage temperatures, (2) transportation of thawed vials at 2°C to 8°C (35°F to 46°F), and (3) anaphylaxis as an adverse reaction for the authorized Pfizer-BioNTech COVID-19 Vaccine under the December 23, 2020 EUA has been granted. In addition, we are notifying you of edits to the EUA Fact Sheet for Recipients, as described below, to clarify VAERS reporting language.

Upon review, we concur that the data that Pfizer submitted for EUA 27034 support (1) that storage of the vials between -96°C to -60°C (-141°F to -76°F) is not considered an excursion from the recommended storage condition, (2) transportation of thawed vials at 2°C to 8°C (35°F to 46°F) for up to 12 hours, and (3) the statement that anaphylaxis has been reported as an adverse reaction. Accordingly, we also concur with the related updates to the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) – EUA Full Prescribing Information to clarify that

storage of the vials between -96°C to -60°C (-141°F to -76°F) is not considered an excursion from the recommended storage condition, that if local redistribution is needed and full cartons containing vials cannot be transported at -90°C to -60°C (-130°F to -76°F), available data support transportation of one or more thawed vials at 2°C to 8°C (35°F to 46°F) for up to 12 hours, and that anaphylaxis has been reported as an adverse reaction for the authorized Pfizer-BioNTech COVID-19 Vaccine. Additionally, the EUA Fact Sheet for Recipients has been edited to say Report vaccine side effects to FDA/CDC Vaccine Adverse Event Reporting System (VAERS). The VAERS toll-free number is 1-800-822-7967 or report online to https://vaers.hhs.gov/reportevent.html.

By submitting these amendments for review by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the December 23, 2020 letter authorizing the emergency use of Pfizer-BioNTech COVID-19 Vaccine.

Sincerely,

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Marion Gruber, Ph.D.
Director
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research