DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

December 22, 2022

Pfizer Inc.
Attention: Gosia Mineo, M.S.
1 Pfizer Way 190/004/4405
Pearl River, NY 10965

Re: EUA 27034 - Emergency Use Authorization of Pfizer-BioNTech COVID-19 Vaccine, Reissued on December 8, 2022, Under Section 564 of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 360bbb-3);
Request in Amendments submitted and received on July 7, 2022, July 28, 2022 and December 15, 2022 to Update the Authorized Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) Emergency Use Authorization (EUA) of Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) Primary Series For 12 Years of Age and Older Dilute Before Use (including Full EUA Prescribing Information)

Dear Ms. Mineo:

This letter is to notify you that we have reviewed the requested changes and data to support the revisions to your Authorized Fact Sheet that pertains to Pfizer COVID-19 Vaccine supplied in multiple dose vials with purple caps, and that your request is granted.

We concur with the updates to the EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) Full EUA Prescribing Information to include the following new information.

19 HOW SUPPLIED/STORAGE AND HANDLING

Frozen Vials Prior to Use

This Section was revised to include the updated expiry dates shown below:

Printed Expiry Date		Updated Expiry Date
12/2021	→	31-Dec-2022
01/2022	→	31-Jan-2023
02/2022	→	28-Feb-2023
03/2022	→	31-Mar-2023
06/2022	→	31-Mar-2023
07/2022	→	30-Apr-2023
08/2022	→	31-May-2023
09/2022	→	30-Jun-2023
10/2022	→	31-Jul-2023
11/2022	→	31-Aug-2023
12/2022	→	30-Sep-2023

Transportation of Thawed Vials

Available data support transportation of one or more thawed vials at 2°C to 8°C (35°F to 46°F) for up to 48 hours.

Related changes were also made to the EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) for consistency. This EUA Fact Sheet has also been updated to include other minor editorial changes.

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 December 8, 2022 letter authorizing the emergency use of Pfizer-BioNTech COVID-19 Vaccine.

Sincerely,

--/S/--

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