DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

April 13, 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 March 29, 2022, Under Section 564 of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 360bbb-3);
Requests in Amendments submitted and received on March 14, 2022 and April 6, 2022 to Update the Authorized Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) - (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 Sheets and that your request is granted.

We concur with the updates to the EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) (Short version) for the two presentations of the Tris/Sucrose formulation (supplied in multiple dose vials with orange caps and labels with an orange border and in multiple dose vials with gray caps and labels with a gray border) to include the following new information.

Vial Storage Prior to Use
Additional text "for up to 12 months from the date of manufacture" was added to indicate that the frozen vials may be stored in an ultra-low temperature freezer at -90ºC to -60ºC (-130ºF to -76ºF) for up to 12 months from the date of manufacture.

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

Printed Manufacturing Date	12-Month Expiry Date
06/2021	31-May-2022
07/2021	30-Jun-2022
08/2021	31-Jul-2022
09/2021	31-Aug-2022
10/2021	30-Sep-2022
11/2021	31-Oct-2022
12/2021	30-Nov-2022
01/2022	31-Dec-2022
02/2022	31-Jan-2023

Related changes were also made to the EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) (Full EUA Prescribing Information) 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 March 29, 2022 letter authorizing the emergency use of Pfizer-BioNTech COVID-19 Vaccine.

Sincerely,

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Peter W. Marks, M.D., Ph.D.
Acting Director
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research