DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

April 26, 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);
Request in Amendment received on March 29, 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 (1) extending the expiry dating period for the PBS/Sucrose formulation (supplied in multiple dose vials with purple caps) from 9 months to 12 months when stored between -90°C to -60°C, and (2) the updates to the EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) (Short Version) for the PBS/Sucrose formulation to include the following new information.

Storage and Handling

Frozen Vials Prior to Use

This Section was revised to add additional printed expiry dates and to include the updated expiry dates as shown below:

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