DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

June 1, 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 May 17, 2022, 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 May 19, 2022 to Update the Authorized Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) - (including Full EUA Prescribing Information) for the PBS/Sucrose formulation - For 12 Years of Age and Older

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) (Full EUA Prescribing Information) to include the following new information.

19 HOW SUPPLIED/STORAGE AND HANDLING

Vial Storage Prior to Use

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

Printed Expiry Date		Updated Expiry Date
06/2022	→	30-Sep-2022
12/2022	→	31-Mar-2023

Related changes were also made to the EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) (short version) for consistency.

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 May 17, 2022 letter authorizing the emergency use of Pfizer-BioNTech COVID-19 Vaccine.

Sincerely,

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