DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

October 18, 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 October 12, 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 September 30, 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) For 12 Years of Age and Older (including Full 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) (Full Prescribing Information) to include the following new information.

19 HOW SUPPLIED/STORAGE AND HANDLING

Frozen Vials Prior to Use

Cartons and vials of Pfizer-BioNTech COVID-19 Vaccine supplied in multiple dose vials with purple caps with an expiry date of December 2021 through December 2022 printed on the label may remain in use beyond the printed date until the updated expiry date shown below; as long as approved storage conditions have been maintained.

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

Related changes were also made to the EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) 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 October 12, 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