DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

September 1, 2021

Pfizer Inc.
Attention: Mr. Amit Patel
235 East 42nd Street
New York, NY 10017

Re: EUA 27034 - Emergency Use Authorization of Pfizer-BioNTech COVID-19 Vaccine, Reissued on August 23, 2021, 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 August 26, 2021 – August 31, 2021 to Update the Authorized Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) - (including Full EUA Prescribing Information), and the Authorized Vaccine Information Fact Sheet for Recipients and Caregivers

Dear Mr. Patel:

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.

6. OVERALL SAFETY SUMMARY

6.2 Post-Authorization Experience

Nervous System Disorders: syncope

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
May 2021	→	August 2021
June 2021	→	September 2021
July 2021	→	October 2021

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

In addition, the EUA Vaccine Information Fact Sheet for Recipients and Caregivers has been revised to include the following new information:

WHAT ARE THE RISKS OF COMIRNATY (COVID-19 VACCINE, mRNA) AND THE PFIZER-BIONTECH COVID-19 VACCINE?

- fainting in association with injection of the vaccine

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 August 23, 2021 letter authorizing the emergency use of Pfizer-BioNTech COVID-19 Vaccine.

Sincerely,

--/S/--

Marion Gruber, Ph.D.
Director
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research