DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

April 6, 2021

Pfizer Inc.
Attention: Ms. Elisa Harkins
500 Arcola Road
Collegeville, PA 19426

**Re:** EUA 27034/115 - Emergency Use Authorization of Pfizer-BioNTech COVID-19 Vaccine, Reissued on February 25, 2021, Under Section 564 of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 360bbb-3);
Requests in Amendments March 15, 2021 - March 25, 2021 to Update the Authorized Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) - (including Full EUA Prescribing Information), and the Authorized Fact Sheet for Recipients and Caregivers

Dear Ms. Harkins:

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) to include the following changes and clarifications. These changes also include revisions requested by FDA:

**Federal COVID-19 Vaccination Program**

- This vaccine is being made available for emergency use through the CDC COVID-19 Vaccination Program (the Vaccination Program);
- Vaccination providers may not charge vaccine recipients any fee for the vaccine and may not charge the vaccine recipient any charge for administration, although they may seek reimbursement from a program or plan that covers COVID-19 vaccine administration fees;
- How to report potential violations of the CDC COVID-19 Vaccination Program requirements.

**Post-Authorization Experience**

- Vomiting, diarrhea, and arm pain were included in the list of adverse reactions that have been reported during post-authorization use of the Pfizer-BioNTech COVID-19 Vaccine.

**Dosage and Administration**

- Illustrations were revised to show gloves being worn for dilution and preparation of doses of the Pfizer-BioNTech COVID-19 Vaccine.

We concur with the updates to the EUA Fact Sheet for Recipients and Caregivers to revise the section "What are the Risks of the Pfizer-BioNTech COVID-19 Vaccine?" to add vomiting, diarrhea, and arm pain as side effects that have been reported with the Pfizer- BioNTech COVID-19 Vaccine and to reorganize the contents of the section. In addition, the EUA Fact Sheet has been updated to clarify that those who receive a COVID-19 vaccine cannot be charged, although vaccination providers may seek reimbursement from a program or plan that covers COVID-19 vaccine administration fees; and how to report cases of suspected fraud.
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 February 25, 2021 letter authorizing the emergency use of Pfizer-BioNTech COVID-19 Vaccine.

Sincerely,

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