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 Sheet that pertains to Pfizer COVID-19 Vaccine supplied in multiple dose vials with purple caps, 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
Frozen Vials Prior to Use

This Section was revised to include the updated expiry dates shown below:
Transportation of Thawed Vials

Available data support transportation of one or more thawed vials at 2°C to 8°C (35°F to 46°F) for up to 48 hours.

Related changes were also made to the EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) for consistency. This EUA Fact Sheet has also been updated to include other minor editorial changes.

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 December 8, 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