



January 06, 2021

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

**Re:** EUA 27034/40 - Requests for Amendments to Update the Authorized Health Care Provider Fact Sheet  
Product Name: Pfizer-BioNTech COVID-19 Vaccine  
Dated: December 28, 2020  
Received: December 28, 2020

Dear Ms. Harkins:

This letter is to notify you that your request to update the EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) to clarify that, after dilution, there are six doses in a vial of the authorized Pfizer-BioNTech COVID-19 Vaccine under the December 23, 2020 [EUA](#) has been granted.

Upon review, we concur that the data that Pfizer submitted for EUA 27034 support the statement that there are six 0.3 mL doses in a vial of Pfizer-BioNTech COVID-19 Vaccine. Accordingly, we also concur with the related updates to the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) that clarify that, after dilution, one vial of Pfizer-BioNTech COVID-19 Vaccine contains six doses of 0.3 mL.

By submitting these amendments for review by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the December 23, 2020, letter authorizing the emergency use of Pfizer-BioNTech COVID-19 Vaccine.

Sincerely,

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Marion Gruber, PhD  
Director  
Office of Vaccines Research and Review  
Center for Biologics Evaluation and Research