



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration Silver Spring MD 20993

June 28, 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 June 17, 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 June 27, 2022 to Update the Authorized Fact Sheet for Recipients and Caregivers About the Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease (COVID-19) for Use in Individuals 6 Months Through 4 Years of Age and the Authorized Fact Sheet for Recipients and Caregivers About the Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease (COVID-19) for Use in Individuals 5 Through 11 Years of Age

Dear Ms. Mineo:

This letter is to notify you that we have reviewed the requested changes and that your request is granted.

We concur with the updates to the EUA Fact Sheets for Recipients and Caregivers to include the following updated information.

**ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES PFIZER-BIONTECH COVID-19 VACCINE?**

Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

By submitting this amendment for review and concurrence by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the June 17, 2022 letter authorizing the emergency use of Pfizer-BioNTech COVID-19 Vaccine.

Sincerely,

Peter Marks, M.D., Ph.D.  
Acting Director  
Office of Vaccines Research and Review  
Center for Biologics Evaluation and Research