



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD

January 31, 2022

Pfizer, Inc.
Attention: Ms. Gosia Mineo, MS
1 Pfizer Way 190/004/4405
Pearl River, NY 10965

Re: EUA 27034 - Emergency Use Authorization of Pfizer-BioNTech COVID-19 Vaccine, Reissued on January 3, 2022, Under Section 564 of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 360bbb-3)
January 31, 2022 Submission to Update the Authorized Fact Sheets for Healthcare Providers Administering Vaccine (Vaccination Providers) – (including Full EUA Prescribing Information) for the two formulations authorized for use in individuals 12 years of age and older and the Authorized Vaccine Information Fact Sheet for Recipients and Caregivers for use in Individuals 12 Years of Age and Older.

Dear Ms. Mineo:

This letter is to notify you that we have granted the following changes to your authorized Fact Sheets as requested by the Food and Drug Administration (FDA).

The EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) (Short Version) for the two formulations authorized for use in individuals 12 years of age and older are revised to include the following new information about SPIKEVAX:

AVAILABLE ALTERNATIVES

COMIRNATY (COVID-19 Vaccine, mRNA) and SPIKEVAX (COVID-19 Vaccine, mRNA) are FDA-approved vaccines to prevent COVID-19 caused by SARS-CoV-2.

Related changes were also made to the EUA Fact Sheets for Healthcare Providers Administering Vaccine (Vaccination Providers) (Full Prescribing Information) for the two formulations authorized for use in individuals 12 years of age and older for consistency. These EUA Fact Sheets for Healthcare Providers Administering Vaccine (Vaccination Providers) have also been updated to include other minor editorial changes.

The Vaccine Information Fact Sheet for Recipients and Caregivers for use in Individuals 12 Years of Age and Older has been revised to include the following new information:

ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES COMIRNATY (COVID-19 VACCINE, mRNA) OR THE PFIZER-BIONTECH COVID-19 VACCINE?

Another choice for preventing COVID-19 is SPIKEVAX, an FDA-approved COVID-19 vaccine.

In addition, minor editorial changes to the Vaccine Information Fact Sheet for Recipients and Caregivers for use in Individuals 12 Years of Age and Older were made for clarity and consistency.

By submitting these amendments for review and concurrence by the FDA, you have complied with the Conditions of Authorization stated in the January 3, 2022, letter re-authorizing the emergency use of Pfizer-BioNTech COVID-19 Vaccine.

Sincerely,

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