



REQUEST FOR COMMENTS AND ADVICE

**COVID-19 VACCINE (PF-07302048)
POSTMARKETING ADVERSE EVENT REPORTING
SEPTEMBER 2021**

090177e197fb0030\Approved\Approved On: 03-Sep-2021 13:06 (GMT)

1. INTRODUCTION

Reference is made to the Biologics License Application (BLA 125742) for COMIRNATY (COVID-19 mRNA Vaccine) approved 23 August 2021 for the prevention of COVID-19 caused by SARS-CoV-2 in individuals ≥ 16 years of age. Reference is also made to the Emergency Use Authorization (EUA 27034) for Pfizer-BioNTech COVID-19 Vaccine for the indication of active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals ≥ 12 years of age issued on 23 August 2021.

Pfizer acknowledges the requirements for reporting adverse events following the recent BLA approval. However, we respectfully need time to make the changes in the safety database while also seeking clarification and verification for specific aspects to reporting below. In the meantime, Pfizer continues to submit cases to the EUA. We are asking for guidance and confirmation from the Agency for the below questions and scenarios.

The purpose of this communication is to obtain FDA agreement and advice regarding the scenarios presented in Section 2.

2. Pfizer's Plan for Reporting Adverse Events

1. Cases where the patient age or age group is reported as less than 16 years, Pfizer will report to the EUA, and if the age or age group is equal to or greater than 16 or is unknown/not reported, Pfizer will report these cases to the BLA.
2. Similarly, cases involving an adverse event where a third dose is administered to immunocompromised patients will be reported to the EUA. If the dose number is not reported or unknown, Pfizer will report those adverse events to the BLA.
3. Per the BLA reporting requirements, cases reported in association with BLA number will be included in PAER.
4. In order to simplify reporting and ensure consistency, if and when additional indications/populations are authorized under the EUA, Pfizer would propose to use the same EUA number.
5. Existing and future Pfizer Interventional studies will be reported to the IND, as well as to the BLA or EUA, depending on the population under investigation.

Pfizer proposes to make these reporting requirements and product configuration changes to the safety system and begin reporting as described above by 24 September 2021. In addition, we would appreciate any additional guidance or clarification from the Agency regarding reporting under the BLA and EUA.

Does CBER agree with Pfizer's proposed plan for reporting adverse events? Pfizer would appreciate a response by 10 September 2021.

Document Approval Record

Document Name:

1.12.4 COVID-19 Vaccine FDA Request for Comments and Advice (Adverse Event Reporting) Sep 2021

Document Title:

1.12.4 COVID-19 Vaccine FDA Request for Comments and Advice (Adverse Event Reporting) Sep 2021

Signed By:

Date(GMT)

Signing Capacity

Pajovich, George N

03-Sep-2021 13:06:30

Business Line Approver

090177e197fb0030\Approved\Approved On: 03-Sep-2021 13:06 (GMT)