Office of Biostatistics and Epidemiology/Division of Epidemiology
Periodic Safety Report Review Checklist

Completed by Reviewer

Product Name	Pfizer-BioNTech COVID-19 Vaccine
Manufacturer	Pfizer
STN #	IND19736.185
DCC Login ID #	955061
Submission Type	**PAER** ☐ **PSUR** ☐ **PBRER** ☐ **PADER** ☐
Submission Format	**ELECTRONIC** ☑ **PAPER** ☐
Reporting Period	**FROM** 12/1/2020 **TO** 12/31/2020
Date Received by FDA	01/15/2021
Date Routed to Reviewer	02/16/2021
Regulatory Information Specialist (RIS) - Name	Ramachandra Naik
Reviewer - Name	Kerry Welsh
Reviewer Signature (electronic signature)	Kerry J. Welsh -S Digitally signed by Kerry J. Welsh -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Kerry J. Welsh -S, 0.9.2342.19200300.100.1.1=2001896608 Date: 2021.02.23 10:36:17 -05'00'

COMMENTS

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1. Countries where the product is licensed or authorized for distribution:

   Not Reported ☐ US ☑ Worldwide ☑

2. Estimated number of doses distributed by reporting period/cumulative:

   Not Reported ☐ US (b) (4) doses

   Not Applicable ☐ Worldwide 26,079,300 doses

3. Does this report describe any actions taken by the manufacturer or other regulatory agency for this product (e.g. labeling changes)? Yes ☑ No ☐

4. Have there been any new safety issues identified by the reviewer in this PSUR? Yes ☑ No ☐

   If YES, please provide pertinent information below AND notify/discuss safety issues with the Team Lead and/or Branch Chief.

Q3. The EUA Fact Sheet for Healthcare Professionals and EUA prescribing information were updated December 23, 2020 to add warnings to monitor vaccine recipients for the occurrence of immediate adverse reactions.
Q4. The following signals were evaluated:
i) Anaphylaxis: considered an Important Identified Risk that was added to the PVP and EUA Fact Sheet
ii) Injection site redness, Injection site swelling, Malaise and Nausea: closed as Identified Risks (Not Important). Reviewer comment: These AEs are included in the EUA Fact Sheet.
iii) Vomiting and Diarrhea: Closed as No Risks
iv) The following are under evaluation as signals: Hypersensitivity (not Anaphylaxis), Insomnia, Injection site pruritus, Pain in the extremity, and Facial paralysis. Reviewer comment: Bell's palsy is included in the EUA Fact Sheet. A recent label update includes hypersensitivity reactions (EUA27034.73).

Conclusions:

☑ The contents of this PSUR/PAER do not indicate a need for further regulatory action.

☐ Please see the following comments and recommendations:

Reference Documents (X:\DE\MEDICAL OFFICER\Guidance Documents):

1. E2C Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs 1996
2. Addendum to E2C Safety Data Management: Periodic Safety Update Reports for Marketed Drugs 2004