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-BioNTech
STN #	19736.243
DCC Login ID #	1005836
Submission Type	**PAER** ☐ **PSUR** ☐ **PBRER** ☑ **PADER** ☐
Submission Format	**ELECTRONIC** ☑ **PAPER** ☐
Reporting Period	**FROM** 02/01/2021 **TO** 02/28/2021
Date Received by FDA	03/15/2021
Date Routed to Reviewer	03/15/2021
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: 2021.03.19 13 34:46 -04'00'

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) cumulative doses

   Not Applicable ☐ Worldwide 126,212,580 cumulative 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.

The following were evaluated as safety topics in the reporting interval:
1) Diarrhoea was evaluated and added to the RSI as an AE (EUA27034.105)
2) Vomiting was evaluated and added to the RSI as an AE (EUA27034.105)
3) Delayed syncope was evaluated and determined not to be a risk
4) Eye pain and eye swelling were evaluated and determined not to be a risk
5) Hearing loss and tinnitus were evaluated and determined not to be a risk
6) Dizziness evaluation is ongoing
7) Immune thrombocytopenia was evaluated and determined not to be a risk
8) Facial paralysis was evaluated and determined not to be a risk, but will be re-evaluated once final safety data from Study C4591001 is available in mid-April 2021

Conclusions:

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

☐ Please see the following comments and recommendations:

9) Herpes Zoster evaluation is ongoing
10) Paraesthesia and dysaesthesia evaluation is ongoing
11) Tachycardia evaluation is ongoing
12) Guillain-Barre syndrome was determined not to be a signal
13) Myocarditis and pericarditis were determined not to be a signal
14) Severe cutaneous adverse reactions were determined not to be a signal

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