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

Completed by Reviewer

Product Name	Human Coronavirus mRNA vaccine in lipid nanoparticles
Manufacturer	Pfizer-BioNTech
STN #	19736/289
DCC Login ID #	Process Track ID: 528778
Submission Type	**PAER** ☐ **PSUR** ☐ **PBRER** ☐ **PADER** ☐
Submission Format	**ELECTRONIC** ☑ **PAPER** ☐
Reporting Period	**FROM** March 1, 2021 **TO** March 31, 2021
Date Received by FDA	April 15, 2021
Date Routed to Reviewer	April 15, 2021
Regulatory Information Specialist (RIS) - Name	Ramachandra Naik
Reviewer - Name	Deborah Thompson
Reviewer Signature (electronic signature)	Deborah L. Thompson -S Digitally signed by Deborah L Thompson S DN: c=US o=U S Government ou=HHS ou=FDA ou=People 0 9 2342 19200300 100 1 1=2002552931 cn=Deborah L Thompson S Date: 2021 04 27 13:44:06 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) current / (b) (4) cumulative

   Not Applicable ☐ Worldwide 120,917,940 current / 243,145,305 cumulative

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 reference safety information (RSI) was updated on March 2, 2021 with the following safety-related changes: diarrhea, pain in extremity (arm), and vomiting (added as adverse reactions in Section 4.8 Undesirable Effects).

Reviewer comment: Section 6.2 of he EUA product labeling was updated with the terms diarrhea, pain in extremity (arm), and vomiting.

In addition, the following safety topics and signals were addressed by the sponsor in his reporting period and will be added to the RSI and proposed local labels "in due course" per labeling and regulatory processes: vaccine stress-related responses, including dizziness, paraesthesia, and tachycardia. Evaluation of hepa ic events, herpes zoster, and seizure is ongoing. The sponsor evaluated the following events and determined hey are not a risk/not a validated signal: delayed skin reactions, extensive swelling of vaccinated limb, reactions associated wi h dermal fillers, thromboembolic events (including those with thrombocytopenia), anosmia, ageusia, arrhythmia, dysphagia, hoarseness, hypertension, hypoglycemia, meningitis, myasthenia gravis, peripheral neuropathy, and transverse myeli is.

The company investigated reports of vials with leakages in Hong Kong (26 vials all from one batch). The root cause of leakage was the combination of the container closure process (crimping) (b) (4) and specific transport conditions (b) (4) . A total of (b) (4) batches were affected and were quarantined. The company excluded any influence on batches that are on market anywhere ou ong Kong and Macau. No batches (b) (4) are currently distributed; (b) (4) .

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