Laura B. Gottschalk -S
2021.09.27 10:29:49 -04'00'

From: Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>
Sent: Tuesday, September 21, 2021 7:44 AM
To: Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>; Patel, Amit <Amitkumar.Patel@pfizer.com>
Cc: Devlin, Carmel M <Carmel.Devlin@pfizer.com>; Pelt, Rich R (b) (6) >; Stafford, Adrienne Kaye <Adrienne.Stafford@pfizer.com>; Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>; Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>
Subject: [EXTERNAL] RE: STN 125742/9 - COVID-19 Vaccine, mRNA (COMIRNATY): Product Correspondence - CBER response to plan for reporting Biologic Product Deviation Reports

Good Morning Laura,

Thank you again for your prior feedback, we do have a couple follow up questions on this.

In CBER's response related to Comment 1, second paragraph, related to "all other reports", there is reference to an additional requirement for all US ICSRs to be submitted as 15-day report independently from seriousness and expectedness. There is reference to multisystem inflammatory syndrome in children. The sub-bullet refers to submit all ICSRs to the BLA number. We are asking clarification and confirmation from the Agency for the below scenario:

- With regards to reporting all serious cases of multisystem inflammatory syndrome in children within 15d, if the patient's age is reported as less than 16 years old, we should submit to the EUA, rather than the BLA. Please confirm.

In the response to Comment 3, CBER requested periodic safety reports to BLA 125742, at monthly intervals, in accordance with 21 CFR 600.80(c)(2), and including consolidated aggregate analysis for all post-marketing and post-authorization spontaneous AE reports:

- Pfizer on behalf of BioNTech understand the FDA's request to mean that the SMSR in its current format fulfills PAER requirements and no separate quarterly PAER is to be submitted. Based on this we will continue to provide the SMSR as described in the EUA Letter of Authorization and including all post-marketing and post-authorization spontaneous cases regardless of application. Please confirm.
- The SMSR will be submitted to BLA 125742 with a cross-reference letter to IND 19736 documenting that it was submitted to the BLA 125742. Please confirm.
- Additionally, Pfizer acknowledges the subsections of SMSR aside from Appendix 2.1 are not needed by FDA; however, we respectfully request to continue to submit the SMSR with all appendices, including 2.1, since it is a global document and the additional Appendices are included at the request of other Health Authorities. Does CBER agree?

As previously communicated, Pfizer will commit to update our systems to report per the BLA and EUA as per 24-Sep-2021. The above special reporting rule will be updated in our system upon clarification from the Agency.

CBER's further clarifications/confirmations are appreciated.

Best regards,
Elisa