Laura B. Gottschalk -S
2021.09.22 09:21:43 -04'00'

From: Gottschalk, Laura
Sent: Wednesday, September 22, 2021 9:12 AM
To: Patel, Amit <Amitkumar.Patel@pfizer.com>
Cc: Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>; Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>; Stafford, Adrienne Kaye <Adrienne.Stafford@pfizer.com>; Pelt, Rich R <(b) (6) >
Subject: RE: [EXTERNAL] RE: STN 125742/5 - COVID-19 Vaccine, mRNA (COMIRNATY): Product Correspondence - CBER Responses to Pfizer/BioNTech's Plan for Reporting Adverse Events

Dear Mr. Patel,

We reference the follow-up questions submitted via email by Ms. Elisa Harkins on September 21, 2021 regarding CBER's responses provided on September 10, 2021 to your request for comments and advice regarding reporting adverse events submitted and received on September 7, 2021 (STN 125742/5). We have the following responses to your follow-up questions:

Pfizer-BioNTech Question 1:
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:

a. *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.*

CBER Response to Question 1:
Please submit ICSRs to VAERS in accordance with 21 CFR 600.80. For serious cases of multisystem inflammatory syndrome in children, if the patient's age is reported as less than 16 years of age, please reference the EUA number (27034) in field G.k.3.3 "Name of Holder/Applicant" in the following format "[name of applicant] EUA NNNNN." Please omit the authorization number field G.k.3.1.

Pfizer-BioNTech Question 2:
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:

a. *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.*

CBER Response to Question 2a:
The monthly report, submitted previously under the EUA as SMSR, can continue to be submitted in the same format described in the EUA, and will fulfill the requirement for the descriptive

information portion of PAER, as described in 21 CFR 600.80(c)(2)(ii)(A). A separate quarterly PAER will not be needed. However, Individual Case Safety Reports (ICSRs) for serious, expected and, nonserious adverse experiences (i.e.., non-expedited ICSRs), as required under the Periodic Reporting requirement (21CFR600.80(c)(2)(ii)(B)), are still required and should be submitted separately from the SMSR (i.e., submit non-expedited ICSRs to VAERS).

b. *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.*

CBER Response to Question 2b:
Yes, this is correct.

c. *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?*

CBER Response to Question 2c:
Yes, CBER agrees.

Please confirm receipt of this communication and let me know if you have any additional questions. If no additional communications are anticipated regarding this Product Correspondence (STN 125742/5), please let me know.

Best regards,
Laura

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