From: Naik, Ramachandra
Sent: Tuesday, July 20, 2021 5:41 PM
To: Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>
Cc: Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>; Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>; Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>
Subject: STN 125742/0 - COMIRNATY BLA – Pediatric PMR studies

Dear Ms. Harkins,

Currently, you are proposing a deferred study C4591007 to evaluate the safety and effectiveness of COMIRNATY in children 11 years of age and younger. Due to time constraints associated with the BLA review, we cannot consider a new request for a partial waiver without risking delayed approval of the BLA. Please submit a revised pediatric plan to indicate that study C4591007, for which the protocol has already been submitted to the IND, will enroll subjects 6 months to 11 years of age and to propose another study to enroll infants <6 months of age, with submission milestone dates in the future. Following approval of your BLA and pending further information about epidemiology of the disease and safety and effectiveness of your vaccine, we would consider a partial waiver and a release from the corresponding PREA PMR.

Please provide your responses, in an amendment to STN 125742/0 by Thursday, July 22, 2021. We recommend that you restate the item and follow it with your explanation or clarification. Use of this format helps organize the relevant information and provides a self-contained document that facilitates future reference.

Please confirm receipt of this email and let me know if you have any questions or need additional information.
Regards,
Ram

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