Information Request

Our Reference: STN: 125752/0

Information Request #1

Date: September 14, 2021

To: Michelle Olsen, Ph.D.
Moderna TX, Inc.
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From: Josephine Resnick, Ph.D.
DVRPA/OVRR/CBER
Email: Josephine.Resnick@fda.hhs.gov

Product: COVID-19 Vaccine, mRNA (SPIKEVAX)

Subject: Pediatric Development Plan Timeline and Revision to Form 3674

Our review of your August 24, 2021 submission (STN 125752/0) is ongoing. We have the following request for additional information:

Please refer to Section 11, Table 5 of your Agreed Initial Pediatric Development Plan (iPSP). Please provide the estimated dates for protocol submission, study initiation, study completion and final study report submission for the following studies:

- A Phase 2/3, randomized, observer-blind, placebocontrolled, dose-finding, age de-escalation study to evaluate safety, reactogenicity, and effectiveness of the mRNA-1273 SARS-CoV-2 vaccine administered as two (or three) doses in healthy children 6 months to <12 years of age.

- Safety and effectiveness study of mRNA-1273 SARS-CoV-2 vaccine administered in healthy infants birth to <6 months of age.

Please confirm that there are no changes to the dates listed for the study "A Phase 2/3, randomized, observer-blind, placebo-controlled study to evaluate safety, reactogenicity, and effectiveness of the mRNA-1273 SARS-CoV-2 vaccine administered as two doses in healthy adolescents 12 to <18 years of age."

Please also refer to form 3674 (Certificate of Compliance). Please submit a revised form which includes all NCT numbers in section 10 of the form.

Please confirm your receipt of this request, and provide your response as an amendment to STN 125742/0 at your earliest convenience but no later than September 21, 2021.

Please contact me if you have questions and include Sudhakar Agnihothram (Sudhakar.Agnihothram@fda.hhs.gov) and Joseph Kulinski (joseph.kulinski@fda.hhs.gov) on all communications.