U.S. FOOD & DRUG ADMINISTRATION

Clarification/Advice

Our Reference: STN: 125752/0

Date: January 11, 2022

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From: **Josephine Resnick, Ph.D.**
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Product: COVID-19 Vaccine, mRNA (SPIKEVAX)

Subject: Datasets

Our review of your August 24, 2021 submission (STN 125752/2) is ongoing. We have the following advice regarding datasets which should be followed in future submissions. No response is required pertaining to this submission, but please acknowledge receipt.

1. As per the COVID-19 TAUG and as per our previous guidance, the CE dataset is an events domain that contains clinical events of interest that would not be classified as adverse events and is assumed to include investigator assessment of events that are included in the protocol as "solicited." In the future, please ensure that you implement reporting investigator obtained solicited reactogenicity events in FACE which is then summarized with the subject's diary data in CE as per our previous requests.

2. Please ensure that if an event is reported in FACE as occurring, for example, on Day 7 (planned time point=Day 7), but is collected on Day 8, that the event be reported in CE as occurring on Day 7, not Day 8.

3. The ongoing flag does not need to be included for the immediate adverse reactions or for any of the other days besides the last day of the solicited assessment period, in this case day 7.

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