RESPONSE TO FDA ON INFORMATION REQUEST#48 RECEIVED ON JANUARY 26, 2022

The Sponsor acknowledges comments on INFORMATION REQUEST#48 DATED 26 JANUARY 2022 in (**BOLD**)

Product: COVID-19 Vaccine, mRNA (SPIKEVAX)

Subject: Clinical data – Unsolicited Adverse Events
In Section 6.1 of your PI, under Unsolicited Adverse Events, in discussion of delayed injection site reactions, the current text reads:

ITEM 1:

Delayed injection site reactions that began >7 days after vaccination were reported in 2.4% of vaccine recipients and 1.4% of placebo recipients.
Please indicate how these percentages were obtained. We note that in Table 14.3.1.21.1.3.3 of your CSR, subjects reporting solicited injection site reactions after any dose with onset >7 days was 1.4% (n=219) in the mRNA-1273 group and 0.7% (n=100) in the placebo group. Please clarify this discrepancy, and if changes are needed, please submit a revised PI for our review.

Sponsor Response:

The data in the PI with regards to delayed injection site reactions that began >7 days after vaccination was based initially on Table 14.3.1.21.1.4, which summarizes solicited adverse reaction that occurs at Day 8 or beyond after each injection. Data post-dose 2 was used in the proposed PI.

The Sponsor would like to clarify that Table 14.3.1.21.1.3.3 of the CSR summarizes Solicited adverse reactions with onset day after Day 7 (delayed reactions began > 7 days) after any dose, and two categories of local adverse reactions are summarized:

- Solicited Local Adverse Reaction includes Pain, Erythema, Swelling, and Axillary Swelling or Tenderness.
- Solicited Injection Site Reaction includes Pain, Erythema, and Swelling.

The PI has been updated to align with Table 14.3.1.21.1.3.3 in the CSR. Redline and clean versions of the PI are provided in this submission.