RESPONSE TO FDA ON INFORMATION REQUEST#46 RECEIVED ON JANUARY 14, 2022

The Sponsor acknowledges comments on INFORMATION REQUEST#46 dated 14 JANUARY 2022 in (**BOLD**)

**Product: COVID-19 Vaccine, mRNA (SPIKEVAX)**

**Subject: Lot release protocol template**

**Our review of your August 16, 2021 submission (STN 125752/1) is ongoing. We have the following request for additional information regarding the lot release protocol template:**

**Please note, the page numbers referenced below are from Adobe page numbering of the LRP template submitted in 125752/0.43.**

**ITEM 1:**

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**Please change "Protocol #:" to "Electronic Filename:" to facilitate future submissions to FDA's electronic gateway.**

**Sponsor Response:**

The Sponsor has replaced "Protocol#:" with "Electronic Filename:" in the Spikevax Lot Release Protocol template (QC-OTH-0609).

**ITEM 2:**

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**Appendix 1, for endotoxin test details for the CX-024414 mRNA:**

- **Please correct the unit of standard endotoxin concentration to EU/mL (not** (b) (4) **).**
- **Please use EU/mL for endotoxin results in the product test summary table.**
- (b) (4) **for the average endotoxin result unit is acceptable because this aligns with the CX-024414 specification** (b) (4)

**Sponsor Response:**

The Sponsor has aligned Appendix 1 of the Spikevax Lot Release Protocol template Bacterial Endotoxins unit of measure to EU/mL for the standard endotoxin concentration and the endotoxin results in the product test summary table.