

RESPONSE TO FDA COMMENTS ON STN 125752 (SPIKEVAX BLA) Information Request # 42b DATED DECEMBER 23, 2021

The Sponsor acknowledges FDA COMMENTS STN 125752\_SPIKEVAX BLA\_ Information Request # 42b DATED 23 DECEMBER 2021 in **(BOLD)**

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

**Subject: Analytical method procedure and validation**

**ITEM 1:**

We have reviewed your December 20, 2021 response to information request (IR) #32, regarding the endotoxin testing of Drug Product (DP) using the (b) (4) [REDACTED] Limulus Amebocyte Lysate (LAL) procedure.

Please provide us with a timeframe (post regulatory action on the BLA) by which you plan on submitting the additional method development/expanded endotoxin testing on whole DP ((b) (4) [REDACTED] procedure).

**Sponsor Response:**

The Sponsor plans to submit additional method development/expanded endotoxin testing on whole DP ((b) (4) [REDACTED] procedure) by June 15, 2022.