



## Clarification/Advice

**Our Reference: STN: 125752/0**

**Date:** October 21, 2021

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

**Subject:** Clarification regarding terminology

Our review of your August 24, 2021 submission (STN 125752/2) is ongoing. We have the following clarification request regarding the regulatory terminology used for the six sections identified as Drug Substances in Module 3 of the BLA:

- In future communications we will refer to the “mRNA-1273 LNP” as the **Drug Substance (DS)**; the “CX-024414” (i.e., mRNA-1273) and the (b) (4) (b) (4); and the lipids “mPEG2000-DMG” (from (b) (4) (b) (4) as **Raw Materials**. Please use this terminology in future communications with the FDA.

Please confirm your receipt of this information, and let me know if you have questions. Please include Sudhakar Agnihothram ([Sudhakar.Agnihothram@fda.hhs.gov](mailto:Sudhakar.Agnihothram@fda.hhs.gov)) and Joseph Kulinski ([joseph.kulinski@fda.hhs.gov](mailto:joseph.kulinski@fda.hhs.gov)) on all communications.