RECORD OF TELECON

Submission ID: *STN 125752*
Office: *OVRR*

Applicant: *ModernaTX Inc*

Telecon Date/Time: *3-NOV-2021 11:00 AM* **Initiated by FDA?:** *Yes*

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Purpose: *External Telecon with Applicant*

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Summary of Discussion:

Discussion regarding implementation of SOP-1142.
Moderna noted the following:

- *SOP 1142 was validated in ModernaTX facility, Norwood, MA*
- *Transfer of SOP 1142 has been completed/Validated at Denham facility, MA*
- *Reason Moderna needs 60 days post approval to implement SOP 1142 for release of SPIKEVAX lots is because NorwoodTX facility is also involved with release of global lots/lots for release under the EUA 27073. Implementation of SOP 1142 will be a global change.*

CBER questioned Moderna on the possibility to implement SOP 1142 at Denham facility, MA, for release testing of SPIKEVAX launch lots (for BLA), right after BLA approval, while the Norwood facility could still possibly continue [pending discussion with FDA on this possibility] to release EUA lots of Moderna COVID-19 Vaccine using SOP 996 until they implement SOP 1142 at the Norwood facility. Moderna responded that they will discuss the feasibility of this option internally and will get back to CBER.

Signature: ____