RECORD OF TELECON

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

Applicant: *ModernaTX Inc*

Telecon Date/Time: *20-JAN-2022 4:00 PM EST* **Initiated by FDA?:** *Yes*

Author: *JOSEPH KULINSKI*
Entered in RMS-BLA: *20-JAN-2022 4:00 PM*
Last Revised: *20-JAN-2022 4:00 PM*

Purpose: *External Telecon with Applicant*

FDA Participants:
SUDHAKAR AGNIHOTHRAM
JOSEPH KULINSKI
MARYNA EICHELBERGER

Sponsor Participants:
MICHELLE OLSEN (REGULATORY)
(b) (6) *(REGULATORY)*
PAUL GRENADILLO (CMC)
JENNIFER WHITE (CMC)
LUIS MUSTAFA (CMC)
PAUL DAWIDCZYK (CMC)

Summary of Discussion:

- No production plans for SPIKEVAX
- No launch lots will be available at the time of a regulatory action
- Moderna does not foresee the demand beyond USG contracts
- If they plan on starting the production of the SPIKEVAX, they will notify CBER
- In the events SPIKEVAX lots will be released, CBER clarified specifics of concurrent testing to Moderna and Moderna agreed to follow the steps outlined by CBER, i.e. DP samples to be sent to CBER before Moderna completes their own testing; once testing is complete LRPs for lots that meet specs should be submitted.

Signature: _____