Date: January 20, 2022
Time: 4:00-4:10pm ET

Attendees:
Moderna
Paul Granadillo, SVP, Global Supply Chain
Jennifer White, SVP, Global Quality
Luis Mustafa, Chief of Staff, CMC
Paul Dawidczyk, VP, CMC Regulatory Affairs
(b) (6)
Michelle Olsen, Associate Director, Regulatory Strategy – Infectious Diseases

CBER
Sudhakar Agnihothram, Biologist (Primary Reviewer), CBER, OVRR
Joseph Kulinski, Biologist (Primary Reviewer), CBER, OVRR
Maryna Eichelberger, Supervisory Microbiologist, DBSQC

Subject: CBER requested an urgent TC to answer two questions:

1. Does Moderna have a plan for 'Launch Lots' of SPIKEVAX once regulatory approval is received?
2. What is the distribution plan for SPIKEVAX with regards to potential concurrent distribution with EUA labelled material?

Summary of Meeting:

Dr. Eichelberger began by asking Moderna about the plans for launch lots. Paul G. responded to the question that Moderna does not have a plan for launch lots. Currently, all planned lots will be used to supply the USG EUA contract and will be supplied over the next 2 months with EUA labelled material.

Dr. Eichelberger next asked about the distribution plan for SPIKEVAX with regards to potential concurrent distribution with EUA labelled material and further asked if we planned to add any indication to the EUA label that the product meets licensing criteria. Paul G. confirmed that there is currently no plan to produce BLA SPIKEVAX labelled material as there is currently no demand for primary series doses beyond what has been supplied under EUA. Also, that we do not have a plan to alter the EUA label. Jenn W. confirmed that in the event that we decide to produce SPIKEVAX material, then we will notify CBER and align the process for lot release before Moderna performs lot release testing. Dr. Eichelberger confirmed that CBER would like to perform lot release testing concurrently with Moderna and that they plan to test (b) (4) the final Drug Product, and not the (b) (4) . Dr. Eichelberger further confirmed that the process should be as follows: Moderna to send DP samples to FDA for concurrent lot release testing; after Moderna concludes testing, the Lot Release Protocol should be sent.

Key take home messages:

1. Moderna does not have a plan for any launch lots
2. Moderna does not have a plan to produce any SPIKEVAX material, as of right now
3. If Moderna plans to produce SPIKEVAX material, we will notify FDA in advance to set up the proper LRP procedure.