



Food & Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

(b) (6) ANALYTICAL METHOD REVIEW MEMO

To: Biologics License Application, STN 125835/0

From: (b) (6)

Through: (b) (6)

Sponsor: ModernaTX, Inc.

Subject: Suitability of lot-release test methods for MNEXSPIKE (mRNA, 2019 novel coronavirus (SARS-CoV-2) mRNA-1283) drug substance and drug product

Recommendation: Approval

Executive Summary:

Analytical methods used for lot release of MNEXSPIKE were reviewed by (b) (6). Their review memoranda are attached to this cover letter.

Conclusion:

The analytical methods and their qualifications reviewed for MNEXSPIKE were found to be adequate for their intended use.