



DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

(b) (6) ANALYTICAL METHOD REVIEW MEMO

To: Biologics License Application, STN 125869/0

From: (b) (6)

Through: (b) (6)

Sponsor: ModernaTX, Inc.

Subject: Suitability of lot-release test methods for MFLUSIVA (mRNA-1010),
(b) (4)
drug product

Recommendation: Approval

Executive Summary:

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

Conclusion:

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