



Our Reference: STN 125869/0
Meeting ID #22382

MEETING SUMMARY
Date: February 17, 2026

ModernaTX, Inc.
Attention: (b) (6)
325 Binney Street
Cambridge, MA 02142

Dear (b) (6) :

Attached is a copy of the memorandum summarizing your February 17, 2026, Type A BLA meeting with CBER. This memorandum constitutes the official record of the meeting. If your understanding of the meeting outcomes differs from those expressed in this summary, it is your responsibility to communicate with CBER as soon as possible. Further, if you require a clarification to a response from a single discipline, you can submit the question via email to the Regulatory Project Manager and we will strive to respond to your inquiry within 3 business days by email.

Please include a reference to Meeting ID# 22382 and BLA 125869/0 in your future submissions related to this product.

If you have any questions, please contact the (b) (6) .

Sincerely,

David C. Kaslow, MD
Director
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research

Meeting Summary

Meeting ID #:	22382
Submission Type & #:	STN 125869/0 Amendment #5
Product Name:	Influenza Vaccine, mRNA (mRNA-1010)
Proposed indication:	Prevention of influenza disease caused by influenza virus subtypes A and type B represented in the vaccine. mRNA-1010 vaccine is intended for use in persons 50 years of age and older.
Applicant:	ModernaTX, Inc.
Meeting Type:	Type A
Meeting Category:	Post-RTF
Meeting Date & Time:	02-17-2026 10:00AM – 10:35AM
Meeting Format:	Virtual Face-to-Face
Meeting Chair:	(b) (6)
Meeting Recorder:	(b) (6)
In-person FDA Attendees:	(b) (6)
	David C. Kaslow, MD
Virtual Applicant Attendees:	(b) (6)

Background and Objectives:

Moderna submitted a Type A meeting request on February 10, 2026. The pre-meeting materials were submitted on February 17, 2026. The purpose of the meeting was to discuss a proposed modification to the regulatory approach of BLA 125869, which Moderna described as intending to align with the benefit-risk considerations across the two age subgroups within the proposed indication (adults ≥50 years). Moderna characterized the submission as follows:

- **Traditional approval for adults 50 through 64 years of age**, based on demonstrated clinical efficacy from Study mRNA-1010-P304; and
- **Accelerated approval for adults 65 years of age and older**, pursuant to 21 CFR 601.41, based on efficacy from the subgroup of adults ≥65 years of age from Study mRNA-1010-P304, in combination with superior immunogenicity (from studies mRNA-1010-P303 Part C and P304) and analyses that demonstrate HAI is a surrogate biomarker reasonably likely to predict clinical benefit. Moderna also proposes a postmarketing requirement (PMR) to confirm clinical effectiveness.

Applicant Questions:

Applicant Question 1:

In light of the revised regulatory approach to the BLA, would the FDA reconsider the RTF determination and proceed with the review of BLA 125869?

Meeting Discussion for Applicant Question 1:

- Moderna presented the following proposed revised regulatory approach for the review of STN 125869/0:
 - The new regulatory approach reflects an independent benefit-risk assessment for two age groups as described in the February 17, 2026 meeting package:
 - Traditional approval for adults 50 through 64 years of age, based on demonstrated clinical efficacy from Study mRNA-1010-P304; and
 - Accelerated approval for adults 65 years of age and older, pursuant to 21 CFR 601.41, based on efficacy from the subgroup of adults ≥65 years of age from Study mRNA-1010-P304, in combination with superior immunogenicity (from studies mRNA-1010-P303 Part C and P304) and analyses that demonstrate HAI is a surrogate biomarker reasonably likely to predict clinical benefit.
- In support of accelerated approval for adults 65 years of age and older, Moderna presented the following rationale supporting their position that mRNA-1010 offers meaningful benefit compared with currently licensed influenza vaccines:
 - Evidence supports superior efficacy in adults >50 years of age compared to licensed standard-dose comparator, as well as superior immunogenicity compared to a high-dose comparator
 - Offers improved adaptability in matching strains to currently circulating influenza strains, including the ability to quickly respond to diverging or pandemic strains.
 - Reduces the reliance on egg-based influenza vaccine production, thus expanding domestic capacity of alternative methods that allow for a more rapid response to emerging influenza vaccines (per a 2019 Presidential Executive Order).
- Moderna proposed to conduct a Real-World Evidence comparative efficacy study as a PMR to support accelerated approval for adults ≥ 65 years of age, with the primary endpoint being relative vaccine effectiveness (rVE) against laboratory-confirmed or medically attended

influenza infection. FDA acknowledged receipt of this proposal in the meeting package and noted that Flublok and FluZone HD would be the appropriate comparators for this study, which should be designed as a pragmatic, randomized study. Any claim of improved strain matching should be formally evaluated within the confirmatory PMR. Complete details would be addressed as part of the BLA review.

Approach:

- Moderna's February 17, 2026, amendment to BLA 125869 includes a proposal to establish two regulatory pathways for review by CBER: traditional approval for adults 50 through 64 years of age; and accelerated approval for adults 65 years of age and older.
- CBER stated that if the amendment is determined to meet the filing requirements, a filing notification will be issued. CBER conveyed that any filing notice would likely contain deficiencies. A potential filing notice would reference this Type A meeting request and summary.
 - Any comments and deficiencies provided in a filing notification will represent a notice that FDA will proceed with review, and there may be additional issues identified as the review progresses.
 - Upon issuance of a filing notification, review of STN 125869/0 would resume.
- CBER intends to hold a Vaccines and Related Biological Products Advisory Committee (VRBPAC) meeting on March 12, 2026, for recommendations on the 2026-2027 Northern Hemisphere Influenza strain selection for currently licensed influenza vaccines (see [Vaccines and Related Biological Products Advisory Committee March 12, 2026 Meeting Announcement - 03/12/2026 | FDA](#)). These recommendations would inform the strain composition of the comparator influenza vaccine(s) to be used in Moderna's pragmatic, randomized postmarketing study. CBER may consider convening a VRBPAC meeting mid-summer 2026 or meet with the Applicant to discuss and make recommendations on the 2026-2027 formula for potential mRNA influenza vaccines licensed for use in the United States during the 2026-2027 influenza season.
- If this application is filed, CBER will assess the need to discuss the submission at an Advisory Committee Meeting.