



Our STN: BL 125869/0

PROPRIETARY NAME ACCEPTABLE

March 5, 2026

ModernaTX, Inc.

Attention: (b) (6)

325 Binney Street

Cambridge, MA 02142

Dear (b) (6) :

Please refer to your Biologics License Application (BLA) received December 5, 2026, submitted under section 351(a) of the Public Health Service Act for Influenza Vaccine, mRNA, requesting a proprietary name review for (b) (4) and MFLUSIVA.

In consultation with Center for Biologics Evaluation and Research's (b) (6) (CBER(b) (6)), we conclude that, under the Federal Food, Drug, and Cosmetic Act and applicable regulations, the determinations for your proposed names are as follows:

- (b) (4) is **Unacceptable**. The name may lead to medication errors due to high phonetic and orthographic similarity to existing marketed pharmaceutical and biologic products such as FLULAVAL.
- **MFLUSIVA** is **Acceptable**.

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

by email.

Sincerely,

(b) (6)

Office of Vaccines Research and Review
Center for Biologics Evaluation and Research