

18 October 2021

AUTHORIZATION LETTER

Marion Gruber, PhD
Director, Office of Vaccines Research and Review
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration
Document Control Center
10903 New Hampshire Avenue
WO71, G112
Silver Spring, MD 20093-0002

Subject: ModernaTX, Inc., BLA Number 125752, mRNA-1273, Information Request #7
Dated 05 October 2021, Sequence Number: N0012

Cc: Paul Dawidczyk, Moderna, Inc.
Email: (b) (6) [@modernatx.com](mailto:(b) (6)@modernatx.com)

Dear Dr. Gruber,

Please accept this Authorization Letter on behalf of Associates of Cape Cod, Inc. (ACC).

ModernaTX, Inc. is hereby authorized to incorporate by reference all relevant chemistry, manufacturing and controls (CMC) information pertaining to endotoxin testing contained in ACC BLA #0700, specifically SN 0006 for ModernaTX, Inc. BLA 125752 for mRNA-1273. ModernaTX also authorizes the FDA to review all relevant information in BLA #0700 in support of BLA# 125752.

ACC requests that all information in this file be treated as confidential to the extent possible in accordance with 21 CFR 314.430 and 21 CFR 20.61, and that no information from this file be provided to any unauthorized persons without written consent.

If there are any questions or additional information, please contact me at 508-540-3444 or at (b) (6) .

Sincerely yours,

(b) (6)

(b) (6)