

**From:** [Vause, Debra](#)  
**To:** [CBER Complicheck](#)  
**Cc:** [Vause, Debra](#)  
**Subject:** URGENT: Compliance Check for BLA 125752/0 - ADD: January 31, 2022  
**Date:** Friday, January 28, 2022 4:58:01 PM  
**Attachments:** [image001.png](#)  
[125752.0.BLA\\_Inspection Waiver\\_Memo \(002\).pdf](#)  
[Moderna norwood endorsment copy1.pdf](#)  
[Lonza endorsment 01282022 c207209 01.pdf](#)  
[eNSpect-Endorsement-Moderna-BLA-STN-125752-0-Aldevron-PLI-Signed.pdf](#)

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Hi,

Please expedite this compliance check request. The ADD is Monday, January 31, 2022.

Please see attached copies of signed endorsements for the following three facilities:

A PLI was conducted at Aldevron, LLC in Fargo, North Dakota on November 1 – 5, 2021. The inspection was classified as NAI and no 483 was issued.

A PLI was conducted at ModernaTX, Inc. in Norwood, Massachusetts on October 25 – 29, 2021. The inspection was classified as NAI and no 483 was issued.

A PLI was conducted at Lonza Biologics, Inc. in Portsmouth, New Hampshire on October 18 – 21, 2021. The inspection was classified as VAI and 483 was issued. All inspectional issues have been resolved.

Also see attached PLI Waiver Memo for the other three facilities (Catalent, Baxter, and Associates of Cape Cod).

Please execute a compliance check.

- **Applicant Name:** ModernaTX, Inc.
- **Product Name:** COVID-19 Vaccine, mRNA
- **License Number:** 2256
- **Address:**  
200 Technology Square  
Cambridge, MA 02139
- **Application #:** 125752/0
- **Projected Approval Date/Action Due Date:** January 31, 2022

**Summary:** Active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older.

**List only those manufacturing locations requiring inspection for an original application approval. List all manufacturing locations affected by the change(s) identified in a supplement:**

- Aldevron, LLC  
4055 41st Avenue South

Fargo, ND 58104  
FEI #: 3015047170

- ModernaTX, Inc.  
One Moderna Way  
Norwood, MA 02062  
FEI #: 3014937058
- Lonza Biologics, Inc.  
101 International Drive  
Portsmouth, NH 03801  
FEI #: 3001451441
- Catalent Biologics, LLC  
1300 S. Patterson Drive  
Bloomington, IN 47403  
FEI #: 3005949964
- Baxter Pharmaceutical Solutions, LLC  
927 S. Curry Pike  
Bloomington, IN 47403  
FEI #: 1000115571
- Associates of Cape Cod  
124 Bernard E. Saint Jean Drive  
East Falmouth, MA 02536  
FEI #: 1219145

Regards, Debbie Vause  
Debra Vause, RN, BSN  
Regulatory Project Manager  
DMPQ/OCBQ/CBER/FDA  
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