

From: [CBER Complicheck](#)
To: [CBER Complicheck](#); [Vause, Debra](#)
Cc: [Sausville, Robert](#); [Anderson, Maria \(CBER\)](#)
Subject: FW: URGENT: Compliance Check for BLA 125752/0 - ADD: January 31, 2022
Date: Friday, January 28, 2022 5:55:28 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](#)

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

There are no ongoing or pending investigations or compliance actions with respect to the above facility or its product(s). Therefore, the Office of Compliance and Biologics Quality, Division of Case Management does not object to the approval of this BLA.

Daniel DeCiero

Consumer Safety Officer
OCBQ/DCM/BDDCB
WO71, Room 5011B
240-402-1666

From: Vause, Debra <Debra.Vause@fda.hhs.gov>
Sent: Friday, January 28, 2022 4:58 PM
To: CBER Complicheck <complicheck@fda.hhs.gov>
Cc: Vause, Debra <Debra.Vause@fda.hhs.gov>
Subject: URGENT: Compliance Check for BLA 125752/0 - ADD: January 31, 2022

Hi,

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

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124 Bernard E. Saint Jean Drive
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FEI #: 1219145

Regards, Debbie Vause
Debra Vause, RN, BSN
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