

DEPARTMENT OF HEALTH AND HUMAN SERVICES
 Food and Drug Administration
APPLICATION TO MARKET A NEW OR ABBREVIATED NEW DRUG OR BIOLOGIC FOR HUMAN USE
(Title 21, Code of Federal Regulations, Parts 314 & 601)

Form Approved: OMB No. 0910-0338
 Expiration Date: March 31, 2020
 See PRA Statement on page 3.

1. Date of Submission (mm/dd/yyyy)
 09/27/2021

APPLICANT INFORMATION	2. Name of Applicant ModernaTx, Inc
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3. Telephone Number (Include country code if applicable and area code) 617-417-4428	4. Facsimile (FAX) Number (Include country code if applicable and area code) (b) (6)
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5. Applicant Address			
Address 1 (Street address, P.O. box, company name c/o) 200 Technology Square		Email Address michelle.olsen@modernatx.com	
Address 2 (Apartment, suite, unit, building, floor, etc.)		Applicant DUNS 069723520	
City Cambridge	State/Province/Region MA	U.S. License Number if previously issued	
Country USA	ZIP or Postal Code 02139		

6. Authorized U.S. Agent (Required for non-U.S. applicants)			
Authorized U.S. Agent Name		Telephone Number (Include area code)	
Address 1 (Street address, P.O. box, company name c/o)		FAX Number (Include area code)	
Address 2 (Apartment, suite, unit, building, floor, etc.)		Email Address	
City	State	U.S. Agent DUNS	
ZIP Code			

PRODUCT DESCRIPTION	7. NDA, ANDA, or BLA Application Number 125752	8. Supplement Number (If applicable)
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9. Established Name (e.g., proper name, USP/USAN name)
 COVID-19 Vaccine

10. Proprietary Name (Trade Name) (If any)
 SPIKEVAX

11. Chemical/Biochemical/Blood Product Name (If any)
 mRNA-1273

12. Dosage Form suspension	13. Strengths 100 mcg	14. Route of Administration intramuscular
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15A. Proposed Indication for Use Active immunization against coronavirus disease 2019 (COVID-19) caused by the SARS-CoV-2 virus in persons 18 years of age and older.	Is this indication for a rare disease (prevalence <200,000 in U.S.)? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
	Does this product have an FDA Orphan Designation for this indication? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	If yes, provide the Orphan Designation number for this indication: <input type="text"/>

Continuation Page for #15

15B. SNOMED CT Indication Disease Term (Use continuation page for each additional indication and respective coded disease term)
 415360003 |Severe acute respiratory syndrome-related coronavirus (organism)|

APPLICATION INFORMATION	16. Application Type (Select one) <input type="checkbox"/> New Drug Application (NDA) <input checked="" type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Abbreviated New Drug Application (ANDA)
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17. If an NDA, identify the type <input type="checkbox"/> 505(b)(1) <input type="checkbox"/> 505(b)(2)	18. If a BLA, identify the type <input checked="" type="checkbox"/> 351(a) <input type="checkbox"/> 351(k)
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19. If a 351(k), identify the biological reference product that is the basis for the submission.
 Name of Biologic: _____ Holder of Licensed Application: _____

20. If an ANDA, or 505(b)(2), identify the listed drug product that is/are the basis for the submission.
 Name of Drug: _____ Application Number of Relied Upon Product: _____
 Indicate Patent Certification: P1 P2 P3 P4 Section viii - MOU Statement of no relevant patents

21. Submission (See instructions) <input type="checkbox"/> Original <input type="checkbox"/> Labeling Supplement <input type="checkbox"/> CMC Supplement <input type="checkbox"/> Efficacy Supplement <input type="checkbox"/> Annual Report <input type="checkbox"/> Product Correspondence <input type="checkbox"/> REMS Supplement <input type="checkbox"/> Postmarketing Requirements or Commitments <input type="checkbox"/> Periodic Safety Report <input type="checkbox"/> Request for Proprietary Name Review <input checked="" type="checkbox"/> Other (Specify): <u>Response to Information Request</u>			
22. Submission Sub-Type <input type="checkbox"/> Presubmission <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Initial Submission <input type="checkbox"/> Resubmission		23. If a supplement, identify the appropriate category. <input type="checkbox"/> CBE <input type="checkbox"/> Prior Approval (PA) <input type="checkbox"/> CBE-30	
24. For Originals and all Supplements, is the product a combination product (21 CFR 3.2(e))? <input type="checkbox"/> Yes <input type="checkbox"/> No		Combination Product Type (See instructions)	Request for Designation (RFD) Number
25. Does the submission contain: Only Pediatric data? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		Human factors information? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	26. Proposed Marketing Status (Select one) <input checked="" type="checkbox"/> Prescription Product (Rx) <input type="checkbox"/> Over-The-Counter Product (OTC)
27. Reasons for Submission Response to Information Request			
28. Establishment Information (Full establishment information should be provided in the body of the application.)			
Establishment Name ModernaTx, Inc.			
Address 1 (Street address, P.O. box, company name c/o) One Moderna Way		Registration (FEI) Number 3014937058	
Address 2 (Apartment, suite, unit, building, floor, etc.) N/A		MF Number 000000	
City Norwood	State/Province/Region MA	Establishment DUNS Number 116912313	
Country USA	ZIP or Postal Code 02062		
Is the establishment new to the application? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		What is the status of the establishment? <input checked="" type="checkbox"/> Pending <input type="checkbox"/> Active <input type="checkbox"/> Inactive <input type="checkbox"/> Withdrawn	
Establishment Contact Information at the site/facility			
Name of Contact for the Establishment Emma Harrington		Telephone Number (Include area code) (b) (6)	
Address 1 (Street address, P.O. box, company name c/o) One Moderna Way		FAX Number (Include area code) 000-000000	
Address 2 (Apartment, suite, unit, building, floor, etc.) N/A		Email Address (b) (6) @modernatx.com	
City Norwood	State/Province/Region MA		
Country USA	ZIP or Postal Code 02062		
Manufacturing Steps and/or Type of Testing Manufacture, Lot Release and Storage of (b) (4), mRNA-1273 LNP Release, stability, in-process testing of (b) (4), mRNA-1273 LNP Lot release stability and release testing of mRNA-1273 Drug Product		Is the site ready for inspection? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A If No, when will site be ready? (mm/dd/yyyy) _____	
Continuation Page for #28			
29. Cross References (List related BLAs, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, MAFs, and DMFs referenced in the current application.) IND# 19365; IND 019745 EUA 027073			
Contin. Page for #29			
30. This application contains the following items (Select all that apply)			
<input type="checkbox"/> 1. Index <input type="checkbox"/> 2. Labeling (Select one): <input type="checkbox"/> Draft Labeling <input type="checkbox"/> Final Printed Labeling <input type="checkbox"/> 3. Summary (21 CFR 314.50 (c))			
<input type="checkbox"/> 4. Chemistry Section <input type="checkbox"/> A. Chemistry, manufacturing, and controls information (e.g., 21 CFR 314.50(d)(1); 21 CFR 601.2) <input type="checkbox"/> B. Samples (21 CFR 314.50 (e)(1); 21 CFR 601.2 (a)) (Submit only upon FDA's request) <input type="checkbox"/> C. Methods validation package (e.g., 21 CFR 314.50(e)(2)(i); 21 CFR 601.2)			
<input type="checkbox"/> 5. Nonclinical pharmacology and toxicology section (e.g., 21 CFR 314.50(d)(2); 21 CFR 601.2)		<input type="checkbox"/> 6. Human pharmacokinetics and bioavailability section (e.g., 21 CFR 314.50(d)(3); 21 CFR 601.2)	
<input type="checkbox"/> 7. Clinical microbiology section (e.g., 21 CFR 314.50(d)(4))		<input type="checkbox"/> 8. Clinical data section (e.g., 21 CFR 314.50(d)(5); 21 CFR 601.2)	
Item 30 continued on page 3			

30. This application contains the following items (Continued; select all that apply)

- | | |
|---|--|
| <input type="checkbox"/> 9. Safety update report (e.g., 21 CFR 314.50(d)(5)(vi)(b); 21 CFR 601.2) | <input type="checkbox"/> 10. Statistical section (e.g., 21 CFR 314.50(d)(6); 21 CFR 601.2) |
| <input type="checkbox"/> 11. Case report tabulations (e.g., 21 CFR 314.50(f)(1); 21 CFR 601.2) | <input type="checkbox"/> 12. Case report forms (e.g., 21 CFR 314.50 (f)(2); 21 CFR 601.2) |
| <input type="checkbox"/> 13. Patent information on any patent that claims the drug/biologic (21 U.S.C. 355(b) or (c)) | <input type="checkbox"/> 14. A patent certification with respect to any patent that claims the drug/biologic (21 U.S.C. 355 (b)(2) or (j)(2)(A)) |
| <input type="checkbox"/> 15. Establishment description (21 CFR Part 600, if applicable) | <input type="checkbox"/> 16. Debarment certification (FD&C Act 306 (k)(1)) |
| <input type="checkbox"/> 17. Field copy certification (21 CFR 314.50 (l)(3)) | <input type="checkbox"/> 18. User Fee Cover Sheet (PDUFA Form FDA 3397, GDUFA Form FDA 3794, BsUFA Form FDA 3792, or MDUFA Form FDA 3601) |
| <input type="checkbox"/> 19. Financial Disclosure Information (21 CFR Part 54) | |
| <input checked="" type="checkbox"/> 20. Other (Specify): <u>Response to Information Request</u> | |

CERTIFICATION

I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to, the following:

1. Good manufacturing practice regulations in 21 CFR Parts 210, 211 or applicable regulations, Parts 606, and/or 820.
2. Biological establishment standards in 21 CFR Part 600.
3. Labeling regulations in 21 CFR Parts 201, 606, 610, 660, and/or 809.
4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR Part 202.
5. Regulations on making changes in application in FD&C Act section 506A, 21 CFR 314.71, 314.72, 314.97, 314.99, and 601.12.
6. Regulations on Reports in 21 CFR 314.80, 314.81, 600.80, and 600.81.
7. Local, state, and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

The data and information in this submission have been reviewed and, to the best of my knowledge, are certified to be true and accurate.

Warning: A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

31. Typed Name and Title of Applicant's Responsible Official Michelle Olsen, Associate Director, Regulatory Affairs	32. Date (mm/dd/yyyy) 09/27/2021
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33. Telephone Number (Include country code if applicable and area code) (617) 417-4428	34. FAX Number (Include country code if applicable and area code) (b) (6)	35. Email Address michelle.olsen@modernatx.com
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36. Address of Applicant's Responsible Official

Address 1 (Street address, P.O. box, company name c/o)
200 Technology Square

Address 2 (Apartment, suite, unit, building, floor, etc.)

City
CambridgeState/Province/Region
MACountry
USAZIP or Postal Code
02139

37. Signature of Applicant's Responsible Official or Other Authorized Official

Sign

Michelle Olsen

Digitally signed by Michelle Olsen
Date: 2021.09.27 17:58:15 -04'00'

38. Countersignature of Authorized U.S. Agent

Sign**The information below applies only to requirements of the Paperwork Reduction Act of 1995.**

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FIRST CONTINUATION PAGE FOR ITEM 28 – Establishment Information

Provide information for additional establishments below, as needed.

Establishment Name

ModernaTx, Inc

Address 1 (Street address, P.O. box, company name c/o)

210 Rustcraft Road

Address 2 (Apartment, suite, unit, building, floor, etc.)

City

Dedham

State/Province/Region

MA

Country

USA

ZIP or Postal Code

02026

Registration (FEI) Number

1111111111

MF Number

000000

Establishment DUNS Number

116912313

Is the establishment new to the application?

 Yes No

What is the status of the establishment?

 Pending Active Inactive Withdrawn

Establishment Contact Information at the site/facility

Name of Contact for the Establishment

Emma Harrington

Address 1 (Street address, P.O. box, company name c/o)

One Moderna Way

Address 2 (Apartment, suite, unit, building, floor, etc.)

City

Norwood

State/Province/Region

MA

Country

USA

ZIP or Postal Code

02062

Telephone Number (Include area code)

(b) (6)

FAX Number (Include area code)

000-000-0000

Email Address

(b) (6) @modernatx.com

Manufacturing Steps and/or Type of Testing

Release, stability, in-process testing of ModernaTX, Inc. Norwood, MA 02062 (b) (4), mRNA-1273 LNP
Stability and release testing of mRNA-1273 Drug ProductIs the site ready for inspection? Yes No N/A

If No, when will site be ready? (mm/dd/yyyy) _____

Establishment Name

Aldevron

Address 1 (Street address, P.O. box, company name c/o)

4055 41st Avenue South

Address 2 (Apartment, suite, unit, building, floor, etc.)

City

Fargo

State/Province/Region

ND

Country

USA

ZIP or Postal Code

58104

Registration (FEI) Number

1111111111

MF Number

000000

Establishment DUNS Number

048764943

Is the establishment new to the application?

 Yes No

What is the status of the establishment?

 Pending Active Inactive Withdrawn

Establishment Contact Information at the site/facility

Name of Contact for the Establishment

(b) (6)

Address 1 (Street address, P.O. box, company name c/o)

4055 41st Avenue South

Address 2 (Apartment, suite, unit, building, floor, etc.)

City

Fargo

State/Province/Region

ND

Country

USA

ZIP or Postal Code

58104

Telephone Number (Include area code)

(b) (6)

FAX Number (Include area code)

000-000-0000

Email Address

(b) (6)

Manufacturing Steps and/or Type of Testing

Manufacture of linearized plasmid DNA (pDNA) template
Release testing of linearized pDNA templateIs the site ready for inspection? Yes No N/A

If No, when will site be ready? (mm/dd/yyyy) _____

Add Second Continuation Page for #28

SECOND CONTINUATION PAGE FOR ITEM 28 – Establishment Information

Provide information for additional establishments below, as needed.

Establishment Name

Lonza Biologics, Inc.

Address 1 (Street address, P.O. box, company name c/o)

101 International Drive

Address 2 (Apartment, suite, unit, building, floor, etc.)

City

Portsmouth

State/Province/Region

NH

Country

USA

ZIP or Postal Code

03801

Registration (FEI) Number

3001451441

MF Number

000000

Establishment DUNS Number

093149750

Is the establishment new to the application?

 Yes No

What is the status of the establishment?

 Pending Active Inactive Withdrawn

Establishment Contact Information at the site/facility

Name of Contact for the Establishment

(b) (6)

Address 1 (Street address, P.O. box, company name c/o)

101 International Drive

Address 2 (Apartment, suite, unit, building, floor, etc.)

City

Portsmouth

State/Province/Region

NH

Country

USA

ZIP or Postal Code

03801

Telephone Number (Include area code)

(b) (6)

FAX Number (Include area code)

000-000-0000

Email Address

(b) (6)

Manufacturing Steps and/or Type of Testing

Manufacture , Release testing, storage of (b) (4) , mRNA-1273 LNP, CX-24414
Stability Testing of CX-24414Is the site ready for inspection? Yes No N/A

If No, when will site be ready? (mm/dd/yyyy) _____

Establishment Name

Associates of Cape Cod

Address 1 (Street address, P.O. box, company name c/o)

124 Bernard Street

Address 2 (Apartment, suite, unit, building, floor, etc.)

Jean Drive

City

East Falmouth

State/Province/Region

MA

Country

USA

ZIP or Postal Code

02536

Registration (FEI) Number

1219145

MF Number

000000

Establishment DUNS Number

076574078

Is the establishment new to the application?

 Yes No

What is the status of the establishment?

 Pending Active Inactive Withdrawn

Establishment Contact Information at the site/facility

Name of Contact for the Establishment

(b) (6)

Address 1 (Street address, P.O. box, company name c/o)

124 Bernard Street

Address 2 (Apartment, suite, unit, building, floor, etc.)

Jean Drive

City

East Falmouth

State/Province/Region

MA

Country

USA

ZIP or Postal Code

02536

Telephone Number (Include area code)

000-000-0000

FAX Number (Include area code)

000-000-0000

Email Address

(b) (6)

Manufacturing Steps and/or Type of Testing

Release and Stability testing of (b) (4) , mRNA-1273 LNP, mRNA-1273 Drug product (bacterial endotoxin)

Is the site ready for inspection? Yes No N/A

If No, when will site be ready? (mm/dd/yyyy) _____

Add Third Continuation Page for #28

THIRD CONTINUATION PAGE FOR ITEM 28 – Establishment Information

Provide information for additional establishments below, as needed.

Establishment Name

Catalant Indiana, LLC (subsidiary of Catalant Pharma Solutions, LLC)

Address 1 (Street address, P.O. box, company name c/o)

1300 South Patterson Drive

Address 2 (Apartment, suite, unit, building, floor, etc.)

City

Bloomington

State/Province/Region

IN

Country

USA

ZIP or Postal Code

47403

Registration (FEI) Number

3005949964

MF Number

000000

Establishment DUNS Number

172209277

Is the establishment new to the application?

 Yes No

What is the status of the establishment?

 Pending Active Inactive Withdrawn

Establishment Contact Information at the site/facility

Name of Contact for the Establishment

(b) (6)

Address 1 (Street address, P.O. box, company name c/o)

1300 S. Patterson Drive

Address 2 (Apartment, suite, unit, building, floor, etc.)

City

Bloomington

State/Province/Region

IN

Country

USA

ZIP or Postal Code

47403

Telephone Number (Include area code)

(b) (6)

FAX Number (Include area code)

000-000-0000

Email Address

(b) (6)

Manufacturing Steps and/or Type of Testing

Fill/Finish, Packaging, Labeling, In-Process testing, Release Testing (Sterility) of Drug Product

Is the site ready for inspection? Yes No N/A

If No, when will site be ready? (mm/dd/yyyy) _____

Establishment Name

Baxter BioPharma Solutions

Address 1 (Street address, P.O. box, company name c/o)

927 S. Curry Pike

Address 2 (Apartment, suite, unit, building, floor, etc.)

City

Bloomington

State/Province/Region

IN

Country

USA

ZIP or Postal Code

47403

Registration (FEI) Number

1000115571

MF Number

000000

Establishment DUNS Number

604719430

Is the establishment new to the application?

 Yes No

What is the status of the establishment?

 Pending Active Inactive Withdrawn

Establishment Contact Information at the site/facility

Name of Contact for the Establishment

(b) (6)

Address 1 (Street address, P.O. box, company name c/o)

927 S. Curry Pike

Address 2 (Apartment, suite, unit, building, floor, etc.)

City

Bloomington

State/Province/Region

IN

Country

USA

ZIP or Postal Code

47403

Telephone Number (Include area code)

(b) (6)

FAX Number (Include area code)

000-000-0000

Email Address

(b) (6)

Manufacturing Steps and/or Type of Testing

Fill/Finish, Packaging, Labeling, In-Process testing, Release Testing (Sterility) of Drug Product

Is the site ready for inspection? Yes No N/A

If No, when will site be ready? (mm/dd/yyyy) _____

Add Fourth Continuation Page for #28