

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)

09/22/2021

APPLICANT INFORMATION

2. Name of Applicant

ModernaTx, Inc

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)

5. Applicant Address

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

200 Technology Square

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

City

Cambridge

State/Province/Region

MA

Country

USA

ZIP or Postal Code

02139

Email Address

michelle.olsen@modernatx.com

Applicant DUNS

069723520

U.S. License Number if previously issued

6. Authorized U.S. Agent (Required for non-U.S. applicants)

Authorized U.S. Agent Name

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

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

City

State

ZIP Code

Telephone Number (Include area code)

FAX Number (Include area code)

Email Address

U.S. Agent DUNS

PRODUCT DESCRIPTION

7. NDA, ANDA, or BLA Application Number

125752

8. Supplement Number (If applicable)

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

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.)? ☐ Yes ☒ NoDoes this product have an FDA
Orphan Designation for this
indication?☐ Yes☒ NoIf yes, provide the Orphan
Designation number for this
indication: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)☐ New Drug Application (NDA)☒ Biologics License Application (BLA)☐ Abbreviated New Drug Application (ANDA)

17. If an NDA, identify the type

☐ 505(b)(1)☐ 505(b)(2)

18. If a BLA, identify the type

☒ 351(a)☐ 351(k)

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 Requests</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 Requests																											
28. Establishment Information (Full establishment information should be provided in the body of the application.)																											
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td colspan="2">Establishment Name ModernaTx, Inc.</td> <td colspan="2">Registration (FEI) Number 3014937058</td> </tr> <tr> <td colspan="2">Address 1 (Street address, P.O. box, company name c/o) One Moderna Way</td> <td colspan="2">MF Number 000000</td> </tr> <tr> <td colspan="2">Address 2 (Apartment, suite, unit, building, floor, etc.) N/A</td> <td colspan="2">Establishment DUNS Number 116912313</td> </tr> <tr> <td>City Norwood</td> <td>State/Province/Region MA</td> <td colspan="2"></td> </tr> <tr> <td>Country USA</td> <td>ZIP or Postal Code 02062</td> <td colspan="2"></td> </tr> <tr> <td colspan="2">Is the establishment new to the application? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</td> <td colspan="2">What is the status of the establishment? <input checked="" type="checkbox"/> Pending <input type="checkbox"/> Active <input type="checkbox"/> Inactive <input type="checkbox"/> Withdrawn</td> </tr> </table>				Establishment Name ModernaTx, Inc.		Registration (FEI) Number 3014937058		Address 1 (Street address, P.O. box, company name c/o) One Moderna Way		MF Number 000000		Address 2 (Apartment, suite, unit, building, floor, etc.) N/A		Establishment DUNS Number 116912313		City Norwood	State/Province/Region MA			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	
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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) _____																									
		<div style="border: 1px solid black; padding: 2px; display: inline-block;">Continuation Page for #28</div>																									
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																											
<div style="border: 1px solid black; padding: 2px; display: inline-block;">Contin. Page for #29</div>																											
30. This application contains the following items (Select all that apply)																											
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td><input type="checkbox"/> 1. Index</td> <td colspan="2"><input type="checkbox"/> 2. Labeling (Select one): <input type="checkbox"/> Draft Labeling <input type="checkbox"/> Final Printed Labeling</td> <td><input type="checkbox"/> 3. Summary (21 CFR 314.50 (c))</td> </tr> <tr> <td><input type="checkbox"/> 4. Chemistry Section</td> <td colspan="3"> <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) </td> </tr> <tr> <td><input type="checkbox"/> 5. Nonclinical pharmacology and toxicology section (e.g., 21 CFR 314.50(d)(2); 21 CFR 601.2)</td> <td colspan="3"><input type="checkbox"/> 6. Human pharmacokinetics and bioavailability section (e.g., 21 CFR 314.50(d)(3); 21 CFR 601.2)</td> </tr> <tr> <td><input type="checkbox"/> 7. Clinical microbiology section (e.g., 21 CFR 314.50(d)(4))</td> <td colspan="3"><input type="checkbox"/> 8. Clinical data section (e.g., 21 CFR 314.50(d)(5); 21 CFR 601.2)</td> </tr> </table>				<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)										
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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 Requests</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) 09/22/2021
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
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 Cambridge	State/Province/Region MA	
Country USA	ZIP or Postal Code 02139	
37. Signature of Applicant's Responsible Official or Other Authorized Official Digitally signed by Michelle Olsen Date: 2021.09.22 15:43:02 -04'00'		38. Countersignature of Authorized U.S. Agent Sign

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

The burden time for this collection of information is estimated to average 24 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to the address to the right:

Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DO NOT SEND YOUR COMPLETED FORM TO THIS PRA STAFF EMAIL ADDRESS.

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			Registration (FEI) Number 1111111111		
Address 2 (Apartment, suite, unit, building, floor, etc.)			MF Number 000000		
City Dedham		State/Province/Region MA		Establishment DUNS Number 116912313	
Country USA		ZIP or Postal Code 02026			
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) 000-000-0000		
Address 2 (Apartment, suite, unit, building, floor, etc.)			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 Release, stability, in-process testing of ModernaTX, Inc. Norwood, MA 02062 (b) (4) mRNA-1273 LNP 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)	
Establishment Name Aldevron					
Address 1 (Street address, P.O. box, company name c/o) 4055 41st Avenue South			Registration (FEI) Number 1111111111		
Address 2 (Apartment, suite, unit, building, floor, etc.)			MF Number 000000		
City Fargo		State/Province/Region ND		Establishment DUNS Number 048764943	
Country USA		ZIP or Postal Code 58104			
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 (b) (6)			Telephone Number (Include area code) (b) (6)		
Address 1 (Street address, P.O. box, company name c/o) 4055 41st Avenue South			FAX Number (Include area code) 000-000-0000		
Address 2 (Apartment, suite, unit, building, floor, etc.)			Email Address (b) (6)		
City Fargo		State/Province/Region ND			
Country USA		ZIP or Postal Code 58104			
Manufacturing Steps and/or Type of Testing Manufacture of linearized plasmid DNA (pDNA) template Release testing of linearized pDNA template				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)	
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)

Telephone Number (Include area code)

(b) (6)

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

101 International Drive

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

FAX Number (Include area code)

000-000-0000

City

Portsmouth

State/Province/Region

NH

Country

USA

ZIP or Postal Code

03801

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-24414

Is the site ready



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)

Telephone Number (Include area code)

000-000-0000

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

124 Bernard Street

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

Jean Drive

FAX Number (Include area code)

000-000-0000

City

East Falmouth

State/Province/Region

MA

Country

USA

ZIP or Postal Code

02536

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



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

Catalent 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)

Telephone Number (Include area code)

(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.)

FAX Number (Include area code)

000-000-0000

City

Bloomington

State/Province/Region

IN

Country

USA

ZIP or Postal Code

47403

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



Yes



No



N/A

for inspection?

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.)

Registration (FEI) Number

1000115571

MF Number

000000

Establishment DUNS Number

604719430

City

Bloomington

State/Province/Region

IN

Country

USA

ZIP or Postal Code

47403

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)

Telephone Number (Include area code)

(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.)

FAX Number (Include area code)

000-000-0000

City

Bloomington

State/Province/Region

IN

Country

USA

ZIP or Postal Code

47403

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



Yes



No



N/A

for inspection?

If No, when will site be

ready? (mm/dd/yyyy)

Add Fourth Continuation Page for #28