

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)

12/20/2021

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) ☐ Original ☐ Labeling Supplement ☐ CMC Supplement ☐ Efficacy Supplement ☐ Annual Report ☐ Product Correspondence ☐ REMS Supplement ☐ Postmarketing Requirements or Commitments ☐ Periodic Safety Report ☐ Request for Proprietary Name Review ☒ Other (Specify): <u>Information Requests #35, #37, and #39</u>																																									
22. Submission Sub-Type ☐ Presubmission ☒ Amendment ☐ Initial Submission ☐ Resubmission		23. If a supplement, identify the appropriate category. ☐ CBE ☐ Prior Approval (PA) ☐ CBE-30																																							
24. For Originals and all Supplements, is the product a combination product (21 CFR 3.2(e))? ☐ Yes ☐ No		Combination Product Type (See instructions)	Request for Designation (RFD) Number																																						
25. Does the submission contain: Only Pediatric data? ☐ Yes ☒ No		Human factors information? ☐ Yes ☒ No	26. Proposed Marketing Status (Select one) ☒ Prescription Product (Rx) ☐ Over-The-Counter Product (OTC)																																						
27. Reasons for Submission IR #35, #37, and #39																																									
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></tr><tr><td colspan="2">Address 1 (Street address, P.O. box, company name c/o) One Moderna Way</td></tr><tr><td colspan="2">Address 2 (Apartment, suite, unit, building, floor, etc.) N/A</td></tr><tr><td>City Norwood</td><td>State/Province/Region MA</td></tr><tr><td>Country USA</td><td>ZIP or Postal Code 02062</td></tr><tr><td colspan="2">Registration (FEI) Number 3014937058</td></tr><tr><td colspan="2">MF Number 000000</td></tr><tr><td colspan="2">Establishment DUNS Number 116912313</td></tr><tr><td colspan="2">Is the establishment new to the application? ☒ Yes ☐ No</td></tr><tr><td colspan="2">What is the status of the establishment? ☒ Pending ☐ Active ☐ Inactive ☐ Withdrawn</td></tr><tr><td colspan="2">Establishment Contact Information at the site/facility</td></tr><tr><td colspan="2">Name of Contact for the Establishment Emma Harrington</td></tr><tr><td colspan="2">Address 1 (Street address, P.O. box, company name c/o) One Moderna Way</td></tr><tr><td colspan="2">Address 2 (Apartment, suite, unit, building, floor, etc.) N/A</td></tr><tr><td>City Norwood</td><td>State/Province/Region MA</td></tr><tr><td>Country USA</td><td>ZIP or Postal Code 02062</td></tr><tr><td colspan="2">Telephone Number (Include area code) (b) (6)</td></tr><tr><td colspan="2">FAX Number (Include area code) 000-000000</td></tr><tr><td colspan="2">Email Address (b) (6) @modernatx.com</td></tr></table>				Establishment Name ModernaTx, Inc.		Address 1 (Street address, P.O. box, company name c/o) One Moderna Way		Address 2 (Apartment, suite, unit, building, floor, etc.) N/A		City Norwood	State/Province/Region MA	Country USA	ZIP or Postal Code 02062	Registration (FEI) Number 3014937058		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.) N/A		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) 000-000000		Email Address (b) (6) @modernatx.com	
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Email Address (b) (6) @modernatx.com																																									
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? ☒ Yes ☐ No ☐ 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)																																									
<table border="1" style="width:100%; border-collapse: collapse;"><tr><td>☐ 1. Index</td><td>☐ 2. Labeling (Select one): ☐ Draft Labeling ☐ Final Printed Labeling</td><td colspan="2">☐ 3. Summary (21 CFR 314.50 (c))</td></tr><tr><td colspan="4">☐ 4. Chemistry Section ☐ A. Chemistry, manufacturing, and controls information (e.g., 21 CFR 314.50(d)(1); 21 CFR 601.2) ☐ B. Samples (21 CFR 314.50 (e)(1); 21 CFR 601.2 (a)) (Submit only upon FDA's request) ☐ C. Methods validation package (e.g., 21 CFR 314.50(e)(2)(i); 21 CFR 601.2)</td></tr><tr><td colspan="2">☐ 5. Nonclinical pharmacology and toxicology section (e.g., 21 CFR 314.50(d)(2); 21 CFR 601.2)</td><td colspan="2">☐ 6. Human pharmacokinetics and bioavailability section (e.g., 21 CFR 314.50(d)(3); 21 CFR 601.2)</td></tr><tr><td colspan="2">☐ 7. Clinical microbiology section (e.g., 21 CFR 314.50(d)(4))</td><td colspan="2">☐ 8. Clinical data section (e.g., 21 CFR 314.50(d)(5); 21 CFR 601.2)</td></tr></table>				☐ 1. Index	☐ 2. Labeling (Select one): ☐ Draft Labeling ☐ Final Printed Labeling	☐ 3. Summary (21 CFR 314.50 (c))		☐ 4. Chemistry Section ☐ A. Chemistry, manufacturing, and controls information (e.g., 21 CFR 314.50(d)(1); 21 CFR 601.2) ☐ B. Samples (21 CFR 314.50 (e)(1); 21 CFR 601.2 (a)) (Submit only upon FDA's request) ☐ C. Methods validation package (e.g., 21 CFR 314.50(e)(2)(i); 21 CFR 601.2)				☐ 5. Nonclinical pharmacology and toxicology section (e.g., 21 CFR 314.50(d)(2); 21 CFR 601.2)		☐ 6. Human pharmacokinetics and bioavailability section (e.g., 21 CFR 314.50(d)(3); 21 CFR 601.2)		☐ 7. Clinical microbiology section (e.g., 21 CFR 314.50(d)(4))		☐ 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)

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

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) 12/20/2021
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: 2021.12.20 15:51:57 -05'00'		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? ☒ 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			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? ☒ 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			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? ☒ 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) 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? ☒ 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			Registration (FEI) Number 3001451441		
Address 2 (Apartment, suite, unit, building, floor, etc.)			MF Number 000000		
City Portsmouth		State/Province/Region NH		Establishment DUNS Number 093149750	
Country USA		ZIP or Postal Code 03801			
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			FAX Number (Include area code) 000-000-0000		
Address 2 (Apartment, suite, unit, building, floor, etc.)			Email Address (b) (6)		
City Portsmouth		State/Province/Region NH			
Country USA		ZIP or Postal Code 03801			
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 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			Registration (FEI) Number 1219145		
Address 2 (Apartment, suite, unit, building, floor, etc.) Jean Drive			MF Number 000000		
City East Falmouth		State/Province/Region MA		Establishment DUNS Number 076574078	
Country USA		ZIP or Postal Code 02536			
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			FAX Number (Include area code) 000-000-0000		
Address 2 (Apartment, suite, unit, building, floor, etc.) Jean Drive			Email Address (b) (6)		
City East Falmouth		State/Province/Region MA			
Country USA		ZIP or Postal Code 02536			
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

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)

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



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



Yes



No



N/A

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

Add Fourth Continuation Page for #28