Next Page | Export Data | Import Data | Reset Form

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)*: 01/17/2022

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 ☑ No

Does this product have an FDA Orphan Designation for this indication? ☐ Yes ☑ No

If 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

Previous Page | Next Page

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)*: Response to Information Request #46

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

Response to Information Request #46

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

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

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)*

☐ 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)*

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)*: Response to Information Request #46	

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	32. Date *(mm/dd/yyyy)*
Michelle Olsen, Associate Director, Regulatory Affairs	01/14/2022

33. Telephone Number *(Include country code if applicable and area code)*	34. FAX Number *(Include country code if applicable and area code)*	35. Email Address
(617) 417-4428	(b) (6)	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	38. Countersignature of Authorized U.S. Agent
Sign Michelle Olsen Digitally signed by Michelle Olsen Date: 2022.01.14 18:06:36 -05'00'	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
PRAStaff@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.

Remove Continuation Page | Return to Form

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 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

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 oflinearized plasmid DNA(pDNA) template
Release testing oflinearized 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

Remove Continuation Page | Return to Form

Remove Continuation Page | Return to Form

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-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

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

Remove Continuation Page | Return to Form

Remove Continuation Page | Return to Form

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 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

Remove Continuation Page | Return to Form