This tracker is meant to assist administrators in tracking punctures of each vial of the Moderna COVID-19 Vaccine.

**KEY INFORMATION**

Each vial can be punctured a **maximum of 20 times**.

If the vial stopper has been punctured 20 times, discard the vial and contents.

Vials should be discarded 12 hours after the first puncture.

This tracker does not provide full information on dosing, administration, storage, or handling of the Moderna COVID-19 Vaccine. Please refer to the attached Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Full EUA Prescribing Information for full details.

For any questions, please contact Moderna Medical Information at **1-866-MODERNA (1-866-663-3762)**

**DOSE TRACKER**

<table>
<thead>
<tr>
<th>Date/Time of First Puncture</th>
<th>1</th>
<th>11</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date/Time of Last Puncture</td>
<td>2</td>
<td>12</td>
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<tr>
<td>Vial #</td>
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</tbody>
</table>

**EMERGENCY USE AUTHORIZATION**

The Moderna COVID-19 Vaccine has not been approved or licensed by the US Food and Drug Administration (FDA), but has been authorized for emergency use by FDA, under an Emergency Use Authorization (EUA), to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 18 years of age and older. The EUA for the Moderna COVID-19 Vaccine is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of the product, unless the declaration is terminated or the authorization is revoked sooner.

*For more information, see Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Full EUA Prescribing Information, Fact Sheet for Recipients and Caregivers, Dear Healthcare Provider Letter, and EUA Letter of Authorization or visit [www.modernatx.com/covid19vaccine-eua](http://www.modernatx.com/covid19vaccine-eua).*

FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS) EMERGENCY USE AUTHORIZATION (EUA) OF THE MODERNA COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, MODERNA COVID-19 VACCINE, for active immunization to prevent COVID-19 in individuals 18 years of age and older.

SUMMARY OF INSTRUCTIONS FOR COVID-19 VACCINATION PROVIDERS
Vaccination providers enrolled in the federal COVID-19 Vaccination Program must report all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults, and cases of COVID-19 that result in hospitalization or death following administration of the Moderna COVID-19 Vaccine. See “MANDATORY REQUIREMENTS FOR MODERNA COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION” for reporting requirements.

The Moderna COVID-19 Vaccine is a suspension for intramuscular injection.

**Primary Series:**
Each primary series dose of the Moderna COVID-19 Vaccine is **0.5 mL**.

The Moderna COVID-19 Vaccine is administered as a primary series of two doses (0.5 mL each) 1 month apart to individuals 18 years of age or older.

A third primary series dose of the Moderna COVID-19 Vaccine (0.5 mL) at least 1 month following the second dose is authorized for administration to individuals at least 18 years of age who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

**Booster Dose:**
The booster dose of the Moderna COVID-19 Vaccine is **0.25 mL**.

A single Moderna COVID-19 Vaccine booster dose (0.25 mL) may be administered intramuscularly at least 6 months after completing a primary series of the Moderna COVID-19 Vaccine to individuals:
- 65 years of age and older
- 18 through 64 years of age at high risk of severe COVID-19
- 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2

A single booster dose of the Moderna COVID-19 Vaccine (0.25 mL) may be administered as a heterologous booster dose following completion of primary vaccination with another authorized or approved COVID-19 vaccine. The eligible population(s) and dosing interval for the

Revised: Oct/20/2021
heterologous booster dose are the same as those authorized for a booster dose of the vaccine used for primary vaccination.

See this Fact Sheet for instructions for preparation and administration. This Fact Sheet may have been updated. For the most recent Fact Sheet, please see www.modernatx.com/covid19vaccine-eua.

For information on clinical trials that are testing the use of the Moderna COVID-19 Vaccine for active immunization against COVID-19, please see www.clinicaltrials.gov.

DESCRIPTION OF COVID-19
Coronavirus disease 2019 (COVID-19) is an infectious disease caused by the novel coronavirus, SARS-CoV-2, that appeared in late 2019. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have reported a wide range of symptoms, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle and body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

DOSAGE AND ADMINISTRATION

Storage and Handling
The information in this Fact Sheet supersedes the information on the vial and carton labels.

During storage, minimize exposure to room light.

The Moderna COVID-19 Vaccine multiple-dose vials are stored frozen between -50° to -15°C (-58° to 5°F). Store in the original carton to protect from light.

Do not store on dry ice or below -50°C (-58°F). Use of dry ice may subject vials to temperatures colder than -50°C (-58°F).

Vials may be stored refrigerated between 2° to 8°C (36° to 46°F) for up to 30 days prior to first use.

Vials may be stored between 8° to 25°C (46° to 77°F) for a total of 24 hours.

After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Vials should be discarded 12 hours after the first puncture.

Thawed vials can be handled in room light conditions.

Do not refreeze once thawed.
Transportation of Thawed Vials at 2° to 8°C (36° to 46°F)

If transport at -50° to -15°C (-58° to 5°F) is not feasible, available data support transportation of one or more thawed vials for up to 12 hours at 2° to 8°C (36° to 46°F) when shipped using shipping containers which have been qualified to maintain 2° to 8°C (36° to 46°F) and under routine road and air transport conditions with shaking and vibration minimized. Once thawed and transported at 2° to 8°C (36° to 46°F), vials should not be refrozen and should be stored at 2° to 8°C (36° to 46°F) until use.

Dosing and Schedule

Primary Series:
Each primary series dose of the Moderna COVID-19 Vaccine is 0.5 mL.

The Moderna COVID-19 Vaccine is administered as a primary series of two doses (0.5 mL each) 1 month apart to individuals 18 years of age or older.

A third primary series dose of the Moderna COVID-19 Vaccine (0.5 mL) at least 1 month following the second dose is authorized for administration to individuals at least 18 years of age who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

Booster Dose:
The booster dose of the Moderna COVID-19 Vaccine is 0.25 mL.

A single Moderna COVID-19 Vaccine booster dose (0.25 mL) may be administered intramuscularly at least 6 months after completing a primary series of the Moderna COVID-19 Vaccine to individuals:
- 65 years of age and older
- 18 through 64 years of age at high risk of severe COVID-19
- 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2

A single booster dose of the Moderna COVID-19 Vaccine (0.25 mL) may be administered as a heterologous booster dose following completion of primary vaccination with another authorized or approved COVID-19 vaccine. The eligible population(s) and dosing interval for the heterologous booster dose are the same as those authorized for a booster dose of the vaccine used for primary vaccination.

Dose Preparation
- The Moderna COVID-19 Vaccine multiple-dose vials contain a frozen suspension that does not contain a preservative and must be thawed prior to administration.
- Remove the required number of vial(s) from storage and thaw each vial before use following the instructions below.
<table>
<thead>
<tr>
<th>Multiple-dose Vials Containing</th>
<th>Thaw in Refrigerator</th>
<th>Thaw at Room Temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.5 mL</td>
<td>Thaw in refrigerated conditions between 2° to 8°C (36° to 46°F) for 2 hours and 30 minutes. Let each vial stand at room temperature for 15 minutes before administering.</td>
<td>Alternatively, thaw at room temperature between 15° to 25°C (59° to 77°F) for 1 hour.</td>
</tr>
<tr>
<td>7.5 mL</td>
<td>Thaw in refrigerated conditions between 2° to 8°C (36° to 46°F) for 3 hours. Let each vial stand at room temperature for 15 minutes before administering.</td>
<td>Alternatively, thaw at room temperature between 15° to 25°C (59° to 77°F) for 1 hour and 30 minutes.</td>
</tr>
</tbody>
</table>

- After thawing, do not refreeze.
- Swirl vial gently after thawing and between each withdrawal. **Do not shake.** Do not dilute the vaccine.
- The Moderna COVID-19 Vaccine is a white to off-white suspension. It may contain white or translucent product-related particulates. Visually inspect the Moderna COVID-19 Vaccine vials for other particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.
- The Moderna COVID-19 Vaccine is supplied in two multiple-dose vial presentations:
  - A multiple-dose vial containing 5.5 mL
  - A multiple-dose vial containing 7.5 mL
- Primary series doses of 0.5 mL and booster doses of 0.25 mL may be extracted from either vial presentation, preferentially using low dead-volume syringes and/or needles.
- When extracting only primary series doses, depending on the syringes and needles used, a maximum of 11 doses (range: 10-11 doses) may be extracted from the vial containing 5.5 mL or a maximum of 15 doses (range: 13-15 doses) may be extracted from the vial containing 7.5 mL.
- When extracting only booster doses or a combination of primary series and booster doses, the maximum number of doses that may be extracted from either vial presentation should not exceed 20 doses. Do not puncture the vial stopper more than 20 times.
- Irrespective of the type of syringe and needle:
  - Each primary series dose must contain 0.5 mL of vaccine.
  - Each booster dose must contain 0.25 mL of vaccine.
  - If the vial stopper has been punctured 20 times, discard the vial and contents.
  - If the amount of vaccine remaining in the vial cannot provide a full dose of 0.5 mL or 0.25 mL, discard the vial and contents. Do not pool excess vaccine from multiple vials.
- After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Record the date and time of first use on the Moderna COVID-19 Vaccine vial label. Discard vial after 12 hours. Do not refreeze.
Administration
Visually inspect each dose of the Moderna COVID-19 Vaccine in the dosing syringe prior to administration. The white to off-white suspension may contain white or translucent product-related particulates. During the visual inspection,

- verify the final dosing volume of 0.5 mL for a primary series dose or 0.25 mL for a booster dose.
- confirm there are no other particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains other particulate matter.

Administer the Moderna COVID-19 Vaccine intramuscularly.

CONTRAINDICATION
Do not administer the Moderna COVID-19 Vaccine to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Moderna COVID-19 Vaccine (see Full EUA Prescribing Information).

WARNINGS

Management of Acute Allergic Reactions
Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Moderna COVID-19 Vaccine.

Monitor Moderna COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention (CDC) guidelines (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html).

Myocarditis and Pericarditis
Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The observed risk is higher among males under 40 years of age than among females and older males. The observed risk is highest in males 18 through 24 years of age. Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae. The CDC has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html).

Syncope
Syncope (fainting) may occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.

Altered Immunocompetence
Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Moderna COVID-19 Vaccine.
Limitations of Vaccine Effectiveness
The Moderna COVID-19 Vaccine may not protect all vaccine recipients.

ADVERSE REACTIONS

Adverse Reactions in Clinical Trials
Adverse reactions reported in clinical trials following administration of the Moderna COVID-19 Vaccine include pain at the injection site, fatigue, headache, myalgia, arthralgia, chills, nausea/vomiting, axillary swelling/tenderness, fever, swelling at the injection site, erythema at the injection site, and rash. (See Full EUA Prescribing Information)

Adverse Reactions in Post-Authorization Experience
Anaphylaxis and other severe allergic reactions, myocarditis, pericarditis, and syncope have been reported following administration of the Moderna COVID-19 Vaccine during mass vaccination outside of clinical trials.

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Moderna COVID-19 Vaccine.

USE WITH OTHER VACCINES
There is no information on the co-administration of the Moderna COVID-19 Vaccine with other vaccines.

INFORMATION TO PROVIDE TO VACCINE RECEPIENTS/CAREGIVERS
As the vaccination provider, you must communicate to the recipient or their caregiver, information consistent with the “Fact Sheet for Recipients and Caregivers” (and provide a copy or direct the individual to the website www.modernatx.com/covid19vaccine-eua to obtain the Fact Sheet) prior to the individual receiving each dose of the Moderna COVID-19 Vaccine, including:

- FDA has authorized the emergency use of the Moderna COVID-19 Vaccine, which is not an FDA-approved vaccine.
- The recipient or their caregiver has the option to accept or refuse the Moderna COVID-19 Vaccine.
- The significant known and potential risks and benefits of the Moderna COVID-19 Vaccine, and the extent to which such risks and benefits are unknown.
- Information about available alternative vaccines and the risks and benefits of those alternatives.

For information on clinical trials that are evaluating the use of the Moderna COVID-19 Vaccine to prevent COVID-19, please see www.clinicaltrials.gov.

Provide a vaccination card to the recipient or their caregiver with the date when the recipient needs to return for the second dose of Moderna COVID-19 Vaccine.

Provide the v-safe information sheet to vaccine recipients/caregivers and encourage vaccine

Revised: Oct/20/2021
Recipients to participate in v-safe. V-safe is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. V-safe asks questions that help CDC monitor the safety of COVID-19 vaccines. V-safe also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information, visit: www.cdc.gov/vsafe.

MANDATORY REQUIREMENTS FOR MODERNA COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION

In order to mitigate the risks of using this unapproved product under EUA and to optimize the potential benefit of the Moderna COVID-19 Vaccine, the following items are required. Use of unapproved Moderna COVID-19 Vaccine for active immunization to prevent COVID-19 under this EUA is limited to the following (all requirements must be met):

1. The Moderna COVID-19 Vaccine is authorized for use in individuals 18 years of age and older.

2. The vaccination provider must communicate to the individual receiving the Moderna COVID-19 Vaccine or their caregiver information consistent with the “Fact Sheet for Recipients and Caregivers” prior to the individual receiving the Moderna COVID-19 Vaccine.

3. The vaccination provider must include vaccination information in the state/local jurisdiction’s Immunization Information System (IIS) or other designated system.

4. The vaccination provider is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS):
   - vaccine administration errors whether or not associated with an adverse event,
   - serious adverse events* (irrespective of attribution to vaccination),
   - cases of Multisystem Inflammatory Syndrome (MIS) in adults, and
   - cases of COVID-19 that result in hospitalization or death.

Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html. For further assistance with reporting to VAERS, call 1-800-822-7967. The reports should include the words “Moderna COVID-19 Vaccine EUA” in the description section of the report.

5. The vaccination provider is responsible for responding to FDA requests for information about vaccine administration errors, adverse events, cases of MIS in adults, and cases of COVID-19 that result in hospitalization or death following administration of the Moderna COVID-19 Vaccine to recipients.

* Serious adverse events are defined as:
   - Death;
   - A life-threatening adverse event;

Revised: Oct/20/2021
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect;
- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.

OTHER ADVERSE EVENT REPORTING TO VAERS AND MODERNATX, INC.
Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

To the extent feasible, report adverse events to ModernaTX, Inc. using the contact information below or by providing a copy of the VAERS form to ModernaTX, Inc.

<table>
<thead>
<tr>
<th>Email</th>
<th>Fax number</th>
<th>Telephone number</th>
</tr>
</thead>
<tbody>
<tr>
<td><a href="mailto:ModernaPV@modernatx.com">ModernaPV@modernatx.com</a></td>
<td>1-866-599-1342</td>
<td>1-866-MODERNA (1-866-663-3762)</td>
</tr>
</tbody>
</table>

ADDITIONAL INFORMATION
For general questions, visit the website or call the telephone number provided below.

To access the most recent Moderna COVID-19 Vaccine Fact Sheets, please scan the QR code or visit the website provided below.

<table>
<thead>
<tr>
<th>Website</th>
<th>Telephone number</th>
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<tbody>
<tr>
<td><a href="http://www.modernatx.com/covid19vaccine-eua">www.modernatx.com/covid19vaccine-eua</a></td>
<td>1-866-MODERNA (1-866-663-3762)</td>
</tr>
</tbody>
</table>

AVAILABLE ALTERNATIVES
Comirnaty (COVID-19 Vaccine, mRNA) is an FDA-approved vaccine to prevent COVID-19 caused by SARS-CoV-2. There may be clinical trials or availability under EUA of other COVID-19 vaccines.

FEDERAL COVID-19 VACCINATION PROGRAM
This vaccine is being made available for emergency use exclusively through the CDC COVID-19 Vaccination Program (the Vaccination Program). Healthcare providers must enroll as providers in the Vaccination Program and comply with the provider requirements. Vaccination providers may not charge any fee for the vaccine and may not charge the vaccine recipient any
out-of-pocket charge for administration. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (private insurance, Medicare, Medicaid, HRSA COVID-19 Uninsured Program for non-insured recipients). For information regarding provider requirements and enrollment in the CDC COVID-19 Vaccination Program, see https://www.cdc.gov/vaccines/covid-19/provider-enrollment.html.

Individuals becoming aware of any potential violations of the CDC COVID-19 Vaccination Program requirements are encouraged to report them to the Office of the Inspector General, U.S. Department of Health and Human Services, at 1-800-HHS-TIPS or TIPS.HHS.GOV.

AUTHORITY FOR ISSUANCE OF THE EUA
The Secretary of the Department of Health and Human Services (HHS) has declared a public health emergency that justifies the emergency use of drugs and biological products during the COVID-19 Pandemic. In response, the FDA has issued an EUA for the unapproved product, Moderna COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals 18 years of age and older.

FDA issued this EUA, based on ModernaTX, Inc.’s request and submitted data.

Although limited scientific information is available, based on the totality of the scientific evidence available to date, it is reasonable to believe that the Moderna COVID-19 Vaccine may be effective for the prevention of COVID-19 in individuals as specified in the Full EUA Prescribing Information.

This EUA for the Moderna COVID-19 Vaccine will end when the Secretary of HHS determines that the circumstances justifying the EUA no longer exist or when there is a change in the approval status of the product such that an EUA is no longer needed.


COUNTERMEASURES INJURY COMPENSATION PROGRAM
The Countermeasures Injury Compensation Program (CICP) is a federal program that has been created to help pay for related costs of medical care and other specific expenses to compensate people injured after use of certain medical countermeasures. Medical countermeasures are specific vaccines, medications, devices, or other items used to prevent, diagnose, or treat the public during a public health emergency or a security threat. For more information about CICP regarding the vaccines to prevent COVID-19, visit http://www.hrsa.gov/cicp, email cicp@hrsa.gov, or call: 1-855-266-2427.

Moderna US, Inc.
Cambridge, MA 02139
END SHORT VERSION FACT SHEET
Long Version (Full EUA Prescribing Information) Begins On Next Page
FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION

MODERNA COVID-19 VACCINE

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3 DOSAGE FORMS AND STRENGTHS
4 CONTRAINDICATIONS
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18 CLINICAL TRIAL RESULTS AND SUPPORTING DATA FOR EUA
   18.1 Efficacy of Two-Dose Primary Series
   18.2 Immunogenicity in Solid Organ Transplant Recipients
   18.3 Immunogenicity of a Booster Dose Following a Moderna COVID-19 Vaccine Primary Series
   18.4 Immunogenicity of a Booster Dose Following Primary Vaccination with Another Authorized or Approved COVID-19 Vaccine
19 HOW SUPPLIED/STORAGE AND HANDLING
20 PATIENT COUNSELING INFORMATION
21 CONTACT INFORMATION

*Sections or subsections omitted from the full prescribing information are not listed

FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION

1 AUTHORIZED USE

Moderna COVID-19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.

2 DOSAGE AND ADMINISTRATION

For intramuscular injection only.

2.1 Preparation for Administration

- The Moderna COVID-19 Vaccine multiple-dose vials contain a frozen suspension that does not contain a preservative and must be thawed prior to administration.
- Remove the required number of vial(s) from storage and thaw each vial before use following the instructions below.
Multiple-dose Vials Containing  

<table>
<thead>
<tr>
<th></th>
<th>Thaw in Refrigerator</th>
<th>Thaw at Room Temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.5 mL</td>
<td>Thaw in refrigerated conditions between 2° to 8°C (36° to 46°F) for 2 hours and 30 minutes. Let each vial stand at room temperature for 15 minutes before administering.</td>
<td>Alternatively, thaw at room temperature between 15° to 25°C (59° to 77°F) for 1 hour.</td>
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<tr>
<td>7.5 mL</td>
<td>Thaw in refrigerated conditions between 2° to 8°C (36° to 46°F) for 3 hours. Let each vial stand at room temperature for 15 minutes before administering.</td>
<td>Alternatively, thaw at room temperature between 15° to 25°C (59° to 77°F) for 1 hour and 30 minutes.</td>
</tr>
</tbody>
</table>

- After thawing, do not refreeze.
- Swirl vial gently after thawing and between each withdrawal. **Do not shake.** Do not dilute the vaccine.
- The Moderna COVID-19 Vaccine is a white to off-white suspension. It may contain white or translucent product-related particulates. Visually inspect the Moderna COVID-19 Vaccine vials for other particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.
- The Moderna COVID-19 Vaccine is supplied in two multiple-dose vial presentations:
  - A multiple-dose vial containing 5.5 mL
  - A multiple-dose vial containing 7.5 mL
- Primary series doses of 0.5 mL and booster doses of 0.25 mL may be extracted from either vial presentation, preferentially using low dead-volume syringes and/or needles.
- When extracting only primary series doses, depending on the syringes and needles used, a maximum of 11 doses (range: 10-11 doses) may be extracted from the vial containing 5.5 mL or a maximum of 15 doses (range: 13-15 doses) may be extracted from the vial containing 7.5 mL.
- When extracting only booster doses or a combination of primary series and booster doses, the maximum number of doses that may be extracted from either vial presentation should not exceed 20 doses. Do not puncture the vial stopper more than 20 times.
- Irrespective of the type of syringe and needle:
  - Each primary series dose must contain 0.5 mL of vaccine.
  - Each booster dose must contain 0.25 mL of vaccine.
  - If the vial stopper has been punctured 20 times, discard the vial and contents.
  - If the amount of vaccine remaining in the vial cannot provide a full dose of 0.5 mL or 0.25 mL, discard the vial and contents. Do not pool excess vaccine from multiple vials.
- After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Record the date and time of first use on the Moderna COVID-19 Vaccine vial label. Discard vial after 12 hours. Do not refreeze.
2.2 Administration

Visually inspect each dose of the Moderna COVID-19 Vaccine in the dosing syringe prior to administration. The white to off-white suspension may contain white or translucent product-related particulates. During the visual inspection,

- verify the final dosing volume of 0.5 mL for a primary series dose or 0.25 mL for a booster dose.
- confirm there are no other particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains other particulate matter.

Administer the Moderna COVID-19 Vaccine intramuscularly.

2.3 Dosing and Schedule

**Primary Series:**
Each primary series dose of the Moderna COVID-19 Vaccine is **0.5 mL**.

The Moderna COVID-19 Vaccine is administered as a primary series of two doses (0.5 mL each) 1 month apart to individuals 18 years of age or older.

A third primary series dose of the Moderna COVID-19 Vaccine (0.5 mL) at least 1 month following the second dose is authorized for administration to individuals at least 18 years of age who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

**Booster Dose:**
The booster dose of the Moderna COVID-19 Vaccine is **0.25 mL**.

A single Moderna COVID-19 Vaccine booster dose (0.25 mL) may be administered intramuscularly at least 6 months after completing a primary series of the Moderna COVID-19 Vaccine to individuals:

- 65 years of age and older
- 18 through 64 years of age at high risk of severe COVID-19
- 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2

A single booster dose of the Moderna COVID-19 Vaccine (0.25 mL) may be administered as a heterologous booster dose following completion of primary vaccination with another authorized or approved COVID-19 vaccine. The eligible population(s) and dosing interval for the heterologous booster dose are the same as those authorized for a booster dose of the vaccine used for primary vaccination.
3 DOSAGE FORMS AND STRENGTHS

Moderna COVID-19 Vaccine is a suspension for intramuscular injection.
- Each primary series dose is 0.5 mL.
- The booster dose is 0.25 mL.

4 CONTRAINDICATIONS

Do not administer the Moderna COVID-19 Vaccine to individuals with a known history of severe allergic reaction (e.g., anaphylaxis) to any component of the Moderna COVID-19 Vaccine [see Description (13)].

5 WARNINGS AND PRECAUTIONS

5.1 Management of Acute Allergic Reactions

Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Moderna COVID-19 Vaccine.

Monitor Moderna COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention (CDC) guidelines (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html).

5.2 Myocarditis and Pericarditis

Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The observed risk is higher among males under 40 years of age than among females and older males. The observed risk is highest in males 18 through 24 years of age. Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae. The CDC has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html).

5.3 Syncope

Syncope (fainting) may occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.

5.4 Altered Immunocompetence

Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a diminished response to the Moderna COVID-19 Vaccine.
5.5 Limitations of Vaccine Effectiveness

The Moderna COVID-19 Vaccine may not protect all vaccine recipients.

6 OVERALL SAFETY SUMMARY

It is MANDATORY for vaccination providers to report to the Vaccine Adverse Event Reporting System (VAERS) all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults, and hospitalized or fatal cases of COVID-19 following vaccination with the Moderna COVID-19 Vaccine. To the extent feasible, provide a copy of the VAERS form to ModernaTX, Inc. Please see the REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS section for details on reporting to VAERS and ModernaTX, Inc.

In a clinical study, the adverse reactions in participants 18 years of age and older following administration of the primary series included pain at the injection site (92.0%), fatigue (70.0%), headache (64.7%), myalgia (61.5%), arthralgia (46.4%), chills (45.4%), nausea/vomiting (23.0%), axillary swelling/tenderness (19.8%), fever (15.5%), swelling at the injection site (14.7%), and erythema at the injection site (10.0%).

In a clinical study, the adverse reactions in participants 18 years of age and older following administration of a booster dose included pain at the injection site (83.8%), fatigue (58.7%), headache (55.1%), myalgia (49.1%), arthralgia (41.3%), chills (35.3%), axillary swelling/tenderness (20.4%), nausea/vomiting (11.4%), fever (6.6%), swelling at the injection site (5.4%), and erythema at the injection site (4.8%), rash (1.8%).

Anaphylaxis and other severe allergic reactions, myocarditis, pericarditis, and syncope have been reported following administration of the Moderna COVID-19 Vaccine outside of clinical trials.

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared with rates in the clinical trials of another vaccine and may not reflect the rates observed in practice.

Overall, 15,419 participants aged 18 years and older received at least one dose of Moderna COVID-19 Vaccine in three clinical trials (NCT04283461, NCT04405076, and NCT04470427). In a fourth clinical trial (NCT04885907), 60 solid organ transplant recipients received a third dose of Moderna COVID-19 Vaccine.

Two-Dose Primary Series

The safety of Moderna COVID-19 Vaccine was evaluated in an ongoing Phase 3 randomized, placebo-controlled, observer-blind clinical trial conducted in the United States involving 30,351 participants 18 years of age and older who received at least one dose (0.5 mL) of Moderna COVID-19 Vaccine (n=15,185) or placebo (n=15,166) (Study 1, NCT04470427). At the time of
vaccination, the mean age of the population was 52 years (range 18-95); 22,831 (75.2%) of participants were 18 to 64 years of age and 7,520 (24.8%) of participants were 65 years of age and older. Overall, 52.7% were male, 47.3% were female, 20.5% were Hispanic or Latino, 79.2% were White, 10.2% were African American, 4.6% were Asian, 0.8% were American Indian or Alaska Native, 0.2% were Native Hawaiian or Pacific Islander, 2.1% were other races, and 2.1% were Multiracial. Demographic characteristics were similar among participants who received Moderna COVID-19 Vaccine and those who received placebo.

Solicited Adverse Reactions

Local and systemic adverse reactions and use of antipyretic medication were solicited in an electronic diary for 7 days following each injection (i.e., day of vaccination and the next 6 days) among participants receiving Moderna COVID-19 Vaccine (n=15,179) and participants receiving placebo (n=15,163) with at least 1 documented dose. Events that persisted for more than 7 days were followed until resolution. Solicited adverse reactions were reported more frequently among vaccine participants than placebo participants.

The reported number and percentage of the solicited local and systemic adverse reactions by age group and dose are presented in Table 1 and Table 2, respectively.

Table 1: Number and Percentage of Participants With Solicited Local and Systemic Adverse Reactions Starting Within 7 Days* After Each Dose in Participants 18-64 Years (Solicited Safety Set, Dose 1 and Dose 2)

<table>
<thead>
<tr>
<th>Local Adverse Reactions</th>
<th>Moderna COVID-19 Vaccine</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Dose 1 (N=11,406) n (%)</td>
<td>Dose 2 (N=10,985) n (%)</td>
</tr>
<tr>
<td>Pain</td>
<td>9,908 (86.9)</td>
<td>9,873 (89.9)</td>
</tr>
<tr>
<td>Pain, Grade 3</td>
<td>366 (3.2)</td>
<td>506 (4.6)</td>
</tr>
<tr>
<td>Axillary swelling/tenderness</td>
<td>1,322 (11.6)</td>
<td>1,775 (16.2)</td>
</tr>
<tr>
<td>Axillary swelling/tenderness, Grade 3</td>
<td>37 (0.3)</td>
<td>46 (0.4)</td>
</tr>
<tr>
<td>Swelling (hardness) ≥25 mm</td>
<td>767 (6.7)</td>
<td>1,389 (12.6)</td>
</tr>
<tr>
<td>Swelling (hardness), Grade 3</td>
<td>62 (0.5)</td>
<td>182 (1.7)</td>
</tr>
<tr>
<td>Erythema (redness) ≥25 mm</td>
<td>344 (3.0)</td>
<td>982 (8.9)</td>
</tr>
<tr>
<td>Erythema (redness), Grade 3</td>
<td>34 (0.3)</td>
<td>210 (1.9)</td>
</tr>
<tr>
<td>Systemic Adverse Reactions</td>
<td>Moderna COVID-19 Vaccine</td>
<td>Placeboa</td>
</tr>
<tr>
<td>----------------------------</td>
<td>--------------------------</td>
<td>----------</td>
</tr>
<tr>
<td></td>
<td>Dose 1 (N=11,406) n (%)</td>
<td>Dose 2 (N=10,985) n (%)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>4,384 (38.4)</td>
<td>7,430 (67.6)</td>
</tr>
<tr>
<td>Fatigue, Grade 3d</td>
<td>120 (1.1)</td>
<td>1,174 (10.7)</td>
</tr>
<tr>
<td>Fatigue, Grade 4e</td>
<td>1 (&lt;0.1)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Headache</td>
<td>4,030 (35.3)</td>
<td>6,898 (62.8)</td>
</tr>
<tr>
<td>Headache, Grade 3d</td>
<td>219 (1.9)</td>
<td>553 (5.0)</td>
</tr>
<tr>
<td>Myalgia</td>
<td>2,699 (23.7)</td>
<td>6,769 (61.6)</td>
</tr>
<tr>
<td>Myalgia, Grade 3d</td>
<td>73 (0.6)</td>
<td>1,113 (10.1)</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>1,893 (16.6)</td>
<td>4,993 (45.5)</td>
</tr>
<tr>
<td>Arthralgia, Grade 3d</td>
<td>47 (0.4)</td>
<td>647 (5.9)</td>
</tr>
<tr>
<td>Arthralgia, Grade 4e</td>
<td>1 (&lt;0.1)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Chills</td>
<td>1,051 (9.2)</td>
<td>5,341 (48.6)</td>
</tr>
<tr>
<td>Chills, Grade 3e</td>
<td>17 (0.1)</td>
<td>164 (1.5)</td>
</tr>
<tr>
<td>Nausea/vomiting</td>
<td>1,068 (9.4)</td>
<td>2,348 (21.4)</td>
</tr>
<tr>
<td>Nausea/vomiting, Grade 3h</td>
<td>6 (&lt;0.1)</td>
<td>10 (&lt;0.1)</td>
</tr>
<tr>
<td>Fever</td>
<td>105 (0.9)</td>
<td>1,908 (17.4)</td>
</tr>
<tr>
<td>Fever, Grade 3f</td>
<td>10 (&lt;0.1)</td>
<td>184 (1.7)</td>
</tr>
<tr>
<td>Fever, Grade 4f</td>
<td>4 (&lt;0.1)</td>
<td>12 (0.1)</td>
</tr>
<tr>
<td>Use of antipyretic or pain medication</td>
<td>2,656 (23.3)</td>
<td>6,292 (57.3)</td>
</tr>
</tbody>
</table>

* 7 days included day of vaccination and the subsequent 6 days. Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary).

a Placebo was a saline solution.

b Grade 3 pain and axillary swelling/tenderness: Defined as any use of prescription pain reliever; prevents daily activity.

c Grade 3 swelling and erythema: Defined as >100 mm / >10 cm.

d Grade 3 fatigue, myalgia, arthralgia: Defined as significant; prevents daily activity.

e Grade 4 fatigue, arthralgia: Defined as requires emergency room visit or hospitalization.

f Grade 3 headache: Defined as significant; any use of prescription pain reliever or prevents daily activity.

g Grade 3 chills: Defined as prevents daily activity and requires medical intervention.
Grade 3 nausea/vomiting: Defined as prevents daily activity; requires outpatient intravenous hydration.

Grade 3 fever: Defined as ≥39.0°C – ≤40.0°C / ≥102.1°F – ≤104.0°F.

Grade 4 fever: Defined as >40.0°C / >104.0°F.

Table 2: Number and Percentage of Participants With Solicited Local and Systemic Adverse Reactions Starting Within 7 Days* After Each Dose in Participants 65 Years and Older (Solicited Safety Set, Dose 1 and Dose 2)

<table>
<thead>
<tr>
<th></th>
<th>Moderna COVID-19 Vaccine</th>
<th>Placebo*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Dose 1 (N=3,762) n (%)</td>
<td>Dose 2 (N=3,692) n (%)</td>
</tr>
<tr>
<td><strong>Local Adverse Reactions</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>2,782 (74.0)</td>
<td>3,070 (83.2)</td>
</tr>
<tr>
<td>Pain, Grade 3b</td>
<td>50 (1.3)</td>
<td>98 (2.7)</td>
</tr>
<tr>
<td>Axillary swelling/tenderness</td>
<td>231 (6.1)</td>
<td>315 (8.5)</td>
</tr>
<tr>
<td>Axillary swelling/tenderness, Grade 3b</td>
<td>12 (0.3)</td>
<td>21 (0.6)</td>
</tr>
<tr>
<td>Swelling (hardness) ≥25 mm</td>
<td>165 (4.4)</td>
<td>400 (10.8)</td>
</tr>
<tr>
<td>Swelling (hardness), Grade 3c</td>
<td>20 (0.5)</td>
<td>72 (2.0)</td>
</tr>
<tr>
<td>Erythema (redness) ≥25 mm</td>
<td>86 (2.3)</td>
<td>275 (7.5)</td>
</tr>
<tr>
<td>Erythema (redness), Grade 3c</td>
<td>8 (0.2)</td>
<td>77 (2.1)</td>
</tr>
<tr>
<td><strong>Systemic Adverse Reactions</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatigue</td>
<td>1,251 (33.3)</td>
<td>2,152 (58.3)</td>
</tr>
<tr>
<td>Fatigue, Grade 3d</td>
<td>30 (0.8)</td>
<td>254 (6.9)</td>
</tr>
<tr>
<td>Headache</td>
<td>921 (24.5)</td>
<td>1,704 (46.2)</td>
</tr>
<tr>
<td>Headache, Grade 3e</td>
<td>52 (1.4)</td>
<td>106 (2.9)</td>
</tr>
<tr>
<td>Myalgia</td>
<td>742 (19.7)</td>
<td>1,739 (47.1)</td>
</tr>
<tr>
<td>Myalgia, Grade 3d</td>
<td>17 (0.5)</td>
<td>205 (5.6)</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>618 (16.4)</td>
<td>1,291 (35.0)</td>
</tr>
<tr>
<td>Arthralgia, Grade 3d</td>
<td>13 (0.3)</td>
<td>123 (3.3)</td>
</tr>
<tr>
<td>Chills</td>
<td>202 (5.4)</td>
<td>1,141 (30.9)</td>
</tr>
<tr>
<td></td>
<td>Moderna COVID-19 Vaccine</td>
<td>Placebo*</td>
</tr>
<tr>
<td>--------------------------</td>
<td>------------------------</td>
<td>----------</td>
</tr>
<tr>
<td></td>
<td>Dose 1 (N=3,762) n (%)</td>
<td>Dose 2 (N=3,692) n (%)</td>
</tr>
<tr>
<td>Chills, Grade 3f</td>
<td>7 (0.2)</td>
<td>27 (0.7)</td>
</tr>
<tr>
<td>Nausea/vomiting</td>
<td>194 (5.2)</td>
<td>437 (11.8)</td>
</tr>
<tr>
<td>Nausea/vomiting, Grade 3g</td>
<td>4 (0.1)</td>
<td>10 (0.3)</td>
</tr>
<tr>
<td>Nausea/vomiting, Grade 4h</td>
<td>0 (0)</td>
<td>1 (&lt;0.1)</td>
</tr>
<tr>
<td>Fever</td>
<td>10 (0.3)</td>
<td>370 (10.0)</td>
</tr>
<tr>
<td>Fever, Grade 3i</td>
<td>1 (&lt;0.1)</td>
<td>18 (0.5)</td>
</tr>
<tr>
<td>Fever, Grade 4j</td>
<td>0 (0)</td>
<td>1 (&lt;0.1)</td>
</tr>
<tr>
<td>Use of antipyretic or pain medication</td>
<td>673 (17.9)</td>
<td>1,546 (41.9)</td>
</tr>
</tbody>
</table>

* 7 days included day of vaccination and the subsequent 6 days. Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary).

a Placebo was a saline solution.
b Grade 3 pain and axillary swelling/tenderness: Defined as any use of prescription pain reliever; prevents daily activity.
c Grade 3 swelling and erythema: Defined as >100 mm / >10 cm.
d Grade 3 fatigue, myalgia, arthralgia: Defined as significant; prevents daily activity.
e Grade 3 headache: Defined as significant; any use of prescription pain reliever or prevents daily activity.
f Grade 3 chills: Defined as prevents daily activity and requires medical intervention.
g Grade 3 nausea/vomiting: Defined as prevents daily activity; requires outpatient intravenous hydration.
h Grade 4 nausea/vomiting: Defined as requires emergency room visit or hospitalization for hypotensive shock.
i Grade 3 fever: Defined as $\geq 39.0^\circ C / \geq 102.1^\circ F$ – $\leq 40.0^\circ C / \leq 104.0^\circ F$.
j Grade 4 fever: Defined as $>40.0^\circ C / >104.0^\circ F$.

Solicited local and systemic adverse reactions reported following administration of Moderna COVID-19 Vaccine had a median duration of 1 to 3 days.

Grade 3 solicited local adverse reactions were more frequently reported after Dose 2 than after Dose 1. Solicited systemic adverse reactions were more frequently reported by vaccine recipients after Dose 2 than after Dose 1.

Unsolicited Adverse Events

Participants were monitored for unsolicited adverse events for up to 28 days following each dose and follow-up is ongoing. Serious adverse events and medically attended adverse events will be recorded for the entire study duration of 2 years. As of November 25, 2020, among participants who had received at least 1 dose of vaccine or placebo (vaccine=15,185, placebo=15,166), unsolicited adverse events that occurred within 28 days following each vaccination were reported by 23.9% of participants (n=3,632) who received Moderna COVID-19 Vaccine and 21.6% of...
participants (n=3,277) who received placebo. In these analyses, 87.9% of study participants had at least 28 days of follow-up after Dose 2.

Lymphadenopathy-related events that were not necessarily captured in the 7-day e-diary were reported by 1.1% of vaccine recipients and 0.6% of placebo recipients. These events included lymphadenopathy, lymphadenitis, lymph node pain, vaccination-site lymphadenopathy, injection-site lymphadenopathy, and axillary mass, which were plausibly related to vaccination. This imbalance is consistent with the imbalance observed for solicited axillary swelling/tenderness in the injected arm.

Hypersensitivity adverse events were reported in 1.5% of vaccine recipients and 1.1% of placebo recipients. Hypersensitivity events in the vaccine group included injection site rash and injection site urticaria, which are likely related to vaccination. Delayed injection site reactions that began >7 days after vaccination were reported in 1.2% of vaccine recipients and 0.4% of placebo recipients. Delayed injection site reactions included pain, erythema, and swelling and are likely related to vaccination.

Throughout the same period, there were three reports of Bell’s palsy in the Moderna COVID-19 Vaccine group (one of which was a serious adverse event), which occurred 22, 28, and 32 days after vaccination, and one in the placebo group which occurred 17 days after vaccination. Currently available information on Bell’s palsy is insufficient to determine a causal relationship with the vaccine.

There were no other notable patterns or numerical imbalances between treatment groups for specific categories of adverse events (including other neurologic, neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Moderna COVID-19 Vaccine.

Serious Adverse Events

As of November 25, 2020, serious adverse events were reported by 1.0% (n=147) of participants who received Moderna COVID-19 Vaccine and 1.0% (n=153) of participants who received placebo, one of which was the case of Bell’s palsy which occurred 32 days following receipt of vaccine.

In these analyses, 87.9% of study participants had at least 28 days of follow-up after Dose 2, and the median follow-up time for all participants was 9 weeks after Dose 2.

There were two serious adverse events of facial swelling in vaccine recipients with a history of injection of dermatological fillers. The onset of swelling was reported 1 and 2 days, respectively, after vaccination and was likely related to vaccination.

There was one serious adverse event of intractable nausea and vomiting in a participant with prior history of severe headache and nausea requiring hospitalization. This event occurred 1 day after vaccination and was likely related to vaccination.

There were no other notable patterns or imbalances between treatment groups for specific
categories of serious adverse events (including neurologic, neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Moderna COVID-19 Vaccine.

**Solid Organ Transplant Recipients**

From an independent study (NCT04885907), in 60 participants who had undergone various solid organ transplant procedures (heart, kidney, kidney-pancreas, liver, lung, pancreas) a median of 3.57 years previously (range 1.99-6.75 years) who received a third vaccine dose (0.5 mL), the adverse event profile was similar to that after the second dose and no Grade 3 or Grade 4 events were reported.

**Booster Dose Following a Primary Series of Moderna COVID-19 Vaccine**

Study 2 is an ongoing Phase 2, randomized, observer-blind, placebo-controlled, dose-confirmation study to evaluate the safety, reactogenicity, and immunogenicity of the Moderna COVID-19 Vaccine in participants 18 years of age and older (NCT04405076). In this study, 198 participants received two doses (0.5 mL, 1 month apart) of the Moderna COVID-19 Vaccine primary series. In an open label-phase, 171 of those participants received a single booster dose (0.25 mL) at least 6 months (range of 5.8 to 8.5 months) after receiving the second dose of the primary series. Safety monitoring after the booster dose was the same as that described for Study 1 participants who received the primary series.

Among the 171 booster dose recipients, the median age was 55 years (range 18-87), 39.2% were male and 60.8% were female, 95.9% were White, 5.8% were Hispanic or Latino, 2.9% were Black or African American, 0.6% were Asian, and 0.6% were American Indian or Alaska Native. Following the booster dose, the median follow-up time was 5.7 months (range of 3.1 to 6.4 months).

**Solicited Adverse Reactions**

Tables 3 and 4 present the frequency and severity of reported solicited local and systemic adverse reactions among Study 2 Moderna COVID-19 Vaccine booster dose recipients 18 to <65 years of age and ≥65 years of age, respectively, within 7 days of a booster vaccination.

**Table 3: Number and Percentage of Study 2 Participants 18-64 Years of Age With Solicited Local and Systemic Adverse Reactions Starting Within 7 Days* After the Booster Dose or After the Second Dose of Primary Series (Solicited Safety Set)**

<table>
<thead>
<tr>
<th>Local Adverse Reactions</th>
<th>Study 2 Second Dose of Primary Series (N=155) n (%)</th>
<th>Study 2 Booster Dose (N=129) n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>137 (88.4)</td>
<td>111 (86.0)</td>
</tr>
<tr>
<td>Pain, Grade 3</td>
<td>1 (0.6)</td>
<td>4 (3.1)</td>
</tr>
<tr>
<td>Axillary swelling/tenderness</td>
<td>18 (11.6)</td>
<td>32 (24.8)</td>
</tr>
<tr>
<td>Axillary swelling/tenderness, Grade 3&lt;sup&gt;a&lt;/sup&gt;</td>
<td>0 (0)</td>
<td>1 (0.8)</td>
</tr>
<tr>
<td>Swelling (hardness) ≥25 mm</td>
<td>16 (10.3)</td>
<td>8 (6.2)</td>
</tr>
<tr>
<td>Erythema (redness) ≥25 mm</td>
<td>12 (7.7)</td>
<td>7 (5.4)</td>
</tr>
<tr>
<td>Erythema (redness), Grade 3&lt;sup&gt;b&lt;/sup&gt;</td>
<td>2 (1.3)</td>
<td>1 (0.8)</td>
</tr>
</tbody>
</table>

**Study 2 Booster Dose (N=129)**

<table>
<thead>
<tr>
<th>Systemic Adverse Reactions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fatigue</td>
</tr>
<tr>
<td>Fatigue, Grade 3&lt;sup&gt;c&lt;/sup&gt;</td>
</tr>
<tr>
<td>Headache</td>
</tr>
<tr>
<td>Headache, Grade 3&lt;sup&gt;d&lt;/sup&gt;</td>
</tr>
<tr>
<td>Myalgia</td>
</tr>
<tr>
<td>Myalgia, Grade 3&lt;sup&gt;c&lt;/sup&gt;</td>
</tr>
<tr>
<td>Arthralgia</td>
</tr>
<tr>
<td>Arthralgia, Grade 3&lt;sup&gt;c&lt;/sup&gt;</td>
</tr>
<tr>
<td>Chills</td>
</tr>
<tr>
<td>Chills, Grade 3&lt;sup&gt;c&lt;/sup&gt;</td>
</tr>
<tr>
<td>Nausea/vomiting</td>
</tr>
<tr>
<td>Fever</td>
</tr>
<tr>
<td>Fever, Grade 3&lt;sup&gt;f&lt;/sup&gt;</td>
</tr>
<tr>
<td>Rash</td>
</tr>
<tr>
<td>Use of antipyretic or pain medication</td>
</tr>
</tbody>
</table>

* 7 days included day of vaccination and the subsequent 6 days. Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary).

<sup>a</sup> Grade 3 pain and axillary swelling/tenderness: Defined as any use of prescription pain reliever; prevents daily activity.

<sup>b</sup> Grade 3 erythema: Defined as >100 mm / >10 cm.

<sup>c</sup> Grade 3 fatigue, myalgia, arthralgia: Defined as significant; prevents daily activity.

<sup>d</sup> Grade 3 headache: Defined as significant; any use of prescription pain reliever or prevents daily activity.

<sup>e</sup> Grade 3 chills: Defined as prevents daily activity and requires medical intervention.

<sup>f</sup> Grade 3 fever: Defined as ≥39.0° – ≤40.0°C / ≥102.1° – ≤104.0°F.

### Table 4: Number and Percentage of Study 2 Participants ≥65 Years of Age With Solicited Local and Systemic Adverse Reactions Starting Within 7 Days* After the Booster Dose or After the Second Dose of Primary Series (Solicited Safety Set)

<table>
<thead>
<tr>
<th>Study 2 Second Dose of Primary Series (N=43)</th>
<th>Study 2 Booster Dose (N=38)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Local Adverse Reactions</strong></td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>32 (74.4)</td>
</tr>
<tr>
<td>Pain, Grade 3&lt;sup&gt;a&lt;/sup&gt;</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Axillary swelling/tenderness</td>
<td>2 (4.7)</td>
</tr>
<tr>
<td>Swelling (hardness) ≥25 mm</td>
<td>5 (11.6)</td>
</tr>
<tr>
<td>Swelling (hardness), Grade 3&lt;sup&gt;b&lt;/sup&gt;</td>
<td>1 (2.3)</td>
</tr>
<tr>
<td>Erythema (redness) ≥25 mm</td>
<td>3 (7.0)</td>
</tr>
<tr>
<td>Erythema (redness), Grade 3&lt;sup&gt;b&lt;/sup&gt;</td>
<td>3 (7.0)</td>
</tr>
</tbody>
</table>

Revised: Oct/20/2021
<table>
<thead>
<tr>
<th>Systemic Adverse Reactions</th>
<th>Study 2 Second Dose of Primary Series (N=43) n (%)</th>
<th>Study 2 Booster Dose (N=38) n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fatigue</td>
<td>23 (53.5)</td>
<td>18 (47.4)</td>
</tr>
<tr>
<td>Fatigue, Grade 3c</td>
<td>2 (4.7)</td>
<td>3 (7.9)</td>
</tr>
<tr>
<td>Myalgia</td>
<td>15 (34.9)</td>
<td>18 (47.4)</td>
</tr>
<tr>
<td>Myalgia, Grade 3c</td>
<td>0 (0)</td>
<td>1 (2.6)</td>
</tr>
<tr>
<td>Headache</td>
<td>17 (39.5)</td>
<td>16 (42.1)</td>
</tr>
<tr>
<td>Headache, Grade 3d</td>
<td>1 (2.3)</td>
<td>1 (2.6)</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>11 (25.6)</td>
<td>15 (39.5)</td>
</tr>
<tr>
<td>Arthralgia, Grade 3c</td>
<td>0 (0)</td>
<td>1 (2.6)</td>
</tr>
<tr>
<td>Chills</td>
<td>7 (16.3)</td>
<td>7 (18.4)</td>
</tr>
<tr>
<td>Nausea/vomiting</td>
<td>5 (11.6)</td>
<td>3 (7.9)</td>
</tr>
<tr>
<td>Fever</td>
<td>2 (4.7)</td>
<td>2 (5.4)</td>
</tr>
<tr>
<td>Fever, Grade 3c</td>
<td>1 (2.3)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Rash</td>
<td>1 (2.3)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Use of antipyretic or pain medication</td>
<td>11 (25.6)</td>
<td>11 (28.9)</td>
</tr>
</tbody>
</table>

* 7 days included day of vaccination and the subsequent 6 days. Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary).

a Grade 3 pain: Defined as any use of prescription pain reliever; prevents daily activity.
b Grade 3 swelling and erythema: Defined as >100 mm / >10 cm.
c Grade 3 fatigue, myalgia, arthralgia: Defined as significant; prevents daily activity.
d Grade 3 headache: Defined as significant; any use of prescription pain reliever or prevents daily activity.
e Grade 3 fever: Defined as ≥39.0° – ≤40.0°C / ≥102.1° – ≤104.0°F.

In participants who received a booster dose, the median duration of solicited local and systemic adverse reactions was 2 to 3 days.

**Unsolicited Adverse Events**

Overall, the 171 participants who received a booster dose, had a median follow-up time of 5.7 months after the booster dose to the cut-off date (August 16, 2021). Through the cut-off date, there were no unsolicited adverse events not already captured as solicited local and systemic reactions that were considered causally related to the Moderna COVID-19 Vaccine.

**Serious Adverse Events**

Of the 171 participants who received a booster dose of Moderna COVID-19 Vaccine, there were no serious adverse events reported from the booster dose through 28 days after the booster dose. Through the cut-off date of August 16, 2021, there were no serious adverse events following the booster dose considered causally related to the Moderna COVID-19 Vaccine.

**Booster Dose Following Primary Vaccination with Another Authorized or Approved COVID-19 Vaccine**

The safety of a Moderna COVID-19 Vaccine (0.25 mL) booster dose in individuals who...
completed primary vaccination with another authorized or approved COVID-19 Vaccine (heterologous booster dose) is inferred from the safety of a Moderna COVID-19 Vaccine (0.25 mL) booster dose administered following completion of a Moderna COVID-19 Vaccine primary series (homologous booster dose) and from data from an independent Phase 1/2 open-label clinical trial (NCT04889209) conducted in the United States that evaluated a heterologous booster dose (0.5 mL) of the Moderna COVID-19 Vaccine. In this study, adults who had completed primary vaccination with a Moderna COVID-19 Vaccine 2-dose series (N=151), a Janssen COVID-19 Vaccine single dose (N=156), or a Pfizer-BioNTech COVID-19 Vaccine 2-dose series (N=151) at least 12 weeks prior to enrollment and who reported no history of SARS-CoV-2 infection were randomized 1:1:1 to receive a booster dose of one of three vaccines: Moderna COVID-19 Vaccine (0.5 mL), Janssen COVID-19 Vaccine, or Pfizer-BioNTech COVID-19 Vaccine. Adverse events were assessed through 28 days after the booster dose. An overall review of adverse reactions reported following the Moderna COVID-19 Vaccine heterologous booster dose (0.5 mL) did not identify any new safety concerns, as compared with adverse reactions reported following Moderna COVID-19 Vaccine primary series doses or homologous booster dose (0.25 mL).

6.2 Post-Authorization Experience

The following adverse reactions have been identified during post-authorization use of the Moderna COVID-19 Vaccine. Because these reactions are reported voluntarily, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure.

Cardiac Disorders: myocarditis, pericarditis
Immune System Disorders: anaphylaxis
Nervous System Disorders: syncope

8 REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS

See Overall Safety Summary (Section 6) for additional information.

The vaccination provider enrolled in the federal COVID-19 Vaccination Program is responsible for the MANDATORY reporting of the listed events following Moderna COVID-19 Vaccine to the Vaccine Adverse Event Reporting System (VAERS)

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events* (irrespective of attribution to vaccination)
- Cases of Multisystem Inflammatory Syndrome (MIS) in adults
- Cases of COVID-19 that results in hospitalization or death

*Serious Adverse Events are defined as:
- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
• A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
• A congenital anomaly/birth defect;
• An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.

Instructions for Reporting to VAERS

The vaccination provider enrolled in the federal COVID-19 Vaccination Program should complete and submit a VAERS form to FDA using one of the following methods:

- Complete and submit the report online: https://vaers.hhs.gov/reportevent.html, or
- If you are unable to submit this form electronically, you may fax it to VAERS at 1-877-721-0366. If you need additional help submitting a report, you may call the VAERS toll-free information line at 1-800-822-7967 or send an email to info@vaers.org.

IMPORTANT: When reporting adverse events or vaccine administration errors to VAERS, please complete the entire form with detailed information. It is important that the information reported to FDA be as detailed and complete as possible. Information to include:

- Patient demographics (e.g., patient name, date of birth)
- Pertinent medical history
- Pertinent details regarding admission and course of illness
- Concomitant medications
- Timing of adverse event(s) in relationship to administration of Moderna COVID-19 Vaccine
- Pertinent laboratory and virology information
- Outcome of the event and any additional follow-up information if it is available at the time of the VAERS report. Subsequent reporting of follow-up information should be completed if additional details become available.

The following steps are highlighted to provide the necessary information for safety tracking:
1. In Box 17, provide information on Moderna COVID-19 Vaccine and any other vaccines administered on the same day; and in Box 22, provide information on any other vaccines received within one month prior.
2. In Box 18, description of the event:
   a. Write “Moderna COVID-19 Vaccine EUA” as the first line
   b. Provide a detailed report of vaccine administration error and/or adverse event. It is important to provide detailed information regarding the patient and adverse event/medication error for ongoing safety evaluation of this unapproved vaccine. Please see information to include listed above.
3. Contact information:
   a. In Box 13, provide the name and contact information of the prescribing healthcare provider or institutional designee who is responsible for the report.
   b. In Box 14, provide the name and contact information of the best doctor/healthcare
professional to contact about the adverse event.

c. In Box 15, provide the address of the facility where vaccine was given (NOT the healthcare provider’s office address).

Other Reporting Instructions

Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

To the extent feasible, report adverse events to ModernaTX, Inc. using the contact information below or by providing a copy of the VAERS form to ModernaTX, Inc.

<table>
<thead>
<tr>
<th>Email</th>
<th>Fax number</th>
<th>Telephone number</th>
</tr>
</thead>
<tbody>
<tr>
<td><a href="mailto:ModernaPV@moderatx.com">ModernaPV@moderatx.com</a></td>
<td>1-866-599-1342</td>
<td>1-866-MODERNA (1-866-663-3762)</td>
</tr>
</tbody>
</table>

10 DRUG INTERACTIONS

There are no data to assess the concomitant administration of the Moderna COVID-19 Vaccine with other vaccines.

11 USE IN SPECIFIC POPULATIONS

11.1 Pregnancy

Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Moderna COVID-19 Vaccine during pregnancy. Women who are vaccinated with Moderna COVID-19 Vaccine during pregnancy are encouraged to enroll in the registry by calling 1-866-MODERNA (1-866-663-3762).

Risk Summary

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively. Available data on Moderna COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.

In a developmental toxicity study, 0.2 mL of a vaccine formulation containing the same quantity of nucleoside-modified messenger ribonucleic acid (mRNA) (100 mcg) and other ingredients included in a single human dose of Moderna COVID-19 Vaccine was administered to female rats by the intramuscular route on four occasions: 28 and 14 days prior to mating, and on gestation days 1 and 13. No vaccine-related adverse effects on female fertility, fetal development, or
postnatal development were reported in the study.

11.2 Lactation

Risk Summary

Data are not available to assess the effects of Moderna COVID-19 Vaccine on the breastfed infant or on milk production/excretion.

11.3 Pediatric Use

Safety and effectiveness have not been assessed in persons less than 18 years of age. Emergency Use Authorization of Moderna COVID-19 Vaccine does not include use in individuals younger than 18 years of age.

11.4 Geriatric Use

Clinical studies of Moderna COVID-19 Vaccine included participants 65 years of age and older receiving vaccine or placebo, and their data contribute to the overall assessment of safety and efficacy. In an ongoing Phase 3 clinical study (Study 1) of primary series dosing (0.5 mL), 24.8% (n=7,520) of participants were 65 years of age and older and 4.6% (n=1,399) of participants were 75 years of age and older. Vaccine efficacy in participants 65 years of age and older was 86.4% (95% CI 61.4, 95.2) compared to 95.6% (95% CI 90.6, 97.9) in participants 18 to <65 years of age [see Clinical Trial Results and Supporting Data for EUA (18)]. Overall, there were no notable differences in the safety profiles observed in participants 65 years of age and older and younger participants [see Overall Safety Summary (6.1)].

In an ongoing Phase 2 clinical study (Study 2) of a single booster dose (0.25 mL), 22.2% (n=38) of participants were 65 years of age and older. This study did not include sufficient numbers of participants 65 years of age and older to determine whether they respond differently than younger participants. Some local and systemic adverse reactions were reported in a lower proportion of participants 65 years of age and older compared to participants 18 through 64 years of age [see Overall Safety Summary (6.1)].

11.5 Use in Immunocompromised

In an independent study, safety and effectiveness of a third 0.5 mL primary series dose of the Moderna COVID-19 Vaccine have been evaluated in participants who received solid organ transplants [see Overall Safety Summary (6.1) and Clinical Trial Results and Supporting Data for EUA (18.2)]. The administration of a third primary series vaccine dose appears to be only moderately effective in increasing antibody titers. Patients should be counseled to maintain physical precautions to help prevent COVID-19. In addition, close contacts of immunocompromised persons should be vaccinated, as appropriate for their health status.

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13 DESCRIPTION

Moderna COVID-19 Vaccine is provided as a white to off-white suspension for intramuscular injection.

Each 0.5 mL dose of Moderna COVID-19 Vaccine contains 100 mcg of nucleoside-modified messenger RNA (mRNA) encoding the pre-fusion stabilized Spike glycoprotein (S) of SARS-CoV-2 virus. Each 0.5 mL dose of the Moderna COVID-19 Vaccine contains the following ingredients: a total lipid content of 1.93 mg (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), 0.31 mg tromethamine, 1.18 mg tromethamine hydrochloride, 0.043 mg acetic acid, 0.20 mg sodium acetate trihydrate, and 43.5 mg sucrose. Each 0.25 mL dose of Moderna COVID-19 Vaccine contains half of these ingredients.

Moderna COVID-19 Vaccine does not contain a preservative.

The vial stoppers are not made with natural rubber latex.

14 CLINICAL PHARMACOLOGY

14.1 Mechanism of Action

The nucleoside-modified mRNA in the Moderna COVID-19 Vaccine is formulated in lipid particles, which enable delivery of the nucleoside-modified mRNA into host cells to allow expression of the SARS-CoV-2 S antigen. The vaccine elicits an immune response to the S antigen, which protects against COVID-19.

18 CLINICAL TRIAL RESULTS AND SUPPORTING DATA FOR EUA

18.1 Efficacy of Two-Dose Primary Series

Study 1 is an ongoing Phase 3 randomized, placebo-controlled, observer-blind clinical trial to evaluate the efficacy, safety, and immunogenicity of the Moderna COVID-19 Vaccine in participants 18 years of age and older in the United States (NCT04470427). Randomization was stratified by age and health risk: 18 to <65 years of age without comorbidities (not at risk for progression to severe COVID-19), 18 to <65 years of age with comorbidities (at risk for progression to severe COVID-19), and 65 years of age and older with or without comorbidities. Participants who were immunocompromised and those with a known history of SARS-CoV-2 infection were excluded from the study. Participants with no known history of SARS-CoV-2 infection but with positive laboratory results indicative of infection at study entry were included. The study allowed for the inclusion of participants with stable pre-existing medical conditions, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 3 months before enrollment, as well as participants with stable human immunodeficiency virus (HIV) infection. A total of 30,420 participants were randomized equally to receive 2 doses of the Moderna COVID-19 Vaccine or saline placebo 1 month apart. Participants will be followed for efficacy and safety until 24 months after the second dose.
The primary efficacy analysis population (referred to as the Per-Protocol Set) included 28,207 participants who received two doses (0.5 mL at 0 and 1 month) of either Moderna COVID-19 Vaccine (n=14,134) or placebo (n=14,073), and had a negative baseline SARS-CoV-2 status. In the Per-Protocol Set, 47.4% were female, 19.7% were Hispanic or Latino; 79.5% were White, 9.7% were African American, 4.6% were Asian, and 2.1% other races. The median age of participants was 53 years (range 18-95) and 25.3% of participants were 65 years of age and older. Of the study participants in the Per-Protocol Set, 18.5% were at increased risk of severe COVID-19 due to at least one pre-existing medical condition (chronic lung disease, significant cardiac disease, severe obesity, diabetes, liver disease, or HIV infection) regardless of age. Between participants who received Moderna COVID-19 Vaccine and those who received placebo, there were no notable differences in demographics or pre-existing medical conditions.

**Efficacy Against COVID-19**

COVID-19 was defined based on the following criteria: The participant must have experienced at least two of the following systemic symptoms: fever (≥38°C / ≥100.4°F), chills, myalgia, headache, sore throat, new olfactory and taste disorder(s); or the participant must have experienced at least one of the following respiratory signs/symptoms: cough, shortness of breath or difficulty breathing, or clinical or radiographical evidence of pneumonia; and the participant must have at least one NP swab, nasal swab, or saliva sample (or respiratory sample, if hospitalized) positive for SARS-CoV-2 by RT-PCR. COVID-19 cases were adjudicated by a Clinical Adjudication Committee.

The median length of follow up for efficacy for participants in the study was 9 weeks post Dose 2. There were 11 COVID-19 cases in the Moderna COVID-19 Vaccine group and 185 cases in the placebo group, with a vaccine efficacy of 94.1% (95% confidence interval of 89.3% to 96.8%).

**Table 5: Primary Efficacy Analysis: COVID-19* in Participants 18 Years of Age and Older Starting 14 Days After Dose 2 per Adjudication Committee Assessments – Per-Protocol Set**

<table>
<thead>
<tr>
<th>Moderna COVID-19 Vaccine</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants (N)</td>
<td>COVID-19 Cases (n)</td>
</tr>
<tr>
<td>14,134</td>
<td>11</td>
</tr>
</tbody>
</table>

* COVID-19: symptomatic COVID-19 requiring positive RT-PCR result and at least two systemic symptoms or one respiratory symptom. Cases starting 14 days after Dose 2.
† VE and 95% CI from the stratified Cox proportional hazard model.

The subgroup analyses of vaccine efficacy are presented in Table 6.

Revised: Oct/20/2021
Table 6: Subgroup Analyses of Vaccine Efficacy: COVID-19* Cases Starting 14 Days After Dose 2 per Adjudication Committee Assessments – Per-Protocol Set

<table>
<thead>
<tr>
<th>Age Subgroup (Years)</th>
<th>Moderna COVID-19 Vaccine</th>
<th>Placebo</th>
<th>% Vaccine Efficacy (95% CI)†</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Participants (N)</td>
<td>COVID-19 Cases (n)</td>
<td>Incidence Rate of COVID-19 per 1,000 Person-Years</td>
</tr>
<tr>
<td>18 to &lt;65</td>
<td>10,551</td>
<td>7</td>
<td>2.875</td>
</tr>
<tr>
<td>≥65</td>
<td>3,583</td>
<td>4</td>
<td>4.595</td>
</tr>
</tbody>
</table>

* COVID-19: symptomatic COVID-19 requiring positive RT-PCR result and at least two systemic symptoms or one respiratory symptom. Cases starting 14 days after Dose 2.
† VE and 95% CI from the stratified Cox proportional hazard model.

Severe COVID-19 was defined based on confirmed COVID-19 as per the primary efficacy endpoint case definition, plus any of the following: Clinical signs indicative of severe systemic illness, respiratory rate ≥30 per minute, heart rate ≥125 beats per minute, SpO2 ≤93% on room air at sea level or PaO2/FIO2 <300 mm Hg; or respiratory failure or ARDS (defined as needing high-flow oxygen, non-invasive or mechanical ventilation, or ECMO), evidence of shock (systolic blood pressure <90 mmHg, diastolic BP <60 mmHg or requiring vasopressors); or significant acute renal, hepatic, or neurologic dysfunction; or admission to an intensive care unit or death.

Among all participants in the Per-Protocol Set analysis, which included COVID-19 cases confirmed by an adjudication committee, no cases of severe COVID-19 were reported in the Moderna COVID-19 Vaccine group compared with 30 cases reported in the placebo group (incidence rate 9.138 per 1,000 person-years). One PCR-positive case of severe COVID-19 in a vaccine recipient was awaiting adjudication at the time of the analysis.

### 18.2 Immunogenicity in Solid Organ Transplant Recipients

An independent randomized-controlled study has been conducted in 120 participants who had undergone various solid organ transplant procedures (heart, kidney, kidney-pancreas, liver, lung, pancreas) a median of 3.57 years previously (range 1.99-6.75 years). A third 0.5 mL primary series dose of the Moderna COVID-19 Vaccine was administered to 60 participants approximately 2 months after they had received a second dose; saline placebo was given to 60 individuals for comparison. Significant increases in levels of SARS-CoV-2 antibodies occurred four weeks after the third dose in 55.0% of participants in the Moderna COVID-19 Vaccine group (33 of 60) and 17.5% of participants in the placebo group (10 of 57).
18.3 Immunogenicity of a Booster Dose Following a Moderna COVID-19 Vaccine Primary Series

Effectiveness of a booster dose of the Moderna COVID-19 Vaccine was based on assessment of neutralizing antibody titers (ID50) against a pseudovirus expressing the SARS-CoV-2 Spike protein from a USA_WA1/2020 isolate carrying the D614G mutation. Immunogenicity analyses compared the ID50 following the booster dose to the ID50 following the primary series.

In an open-label phase of Study 2, participants 18 years of age and older received a single booster dose (0.25 mL) at least 6 months after completion of the primary series (two doses of 0.5 mL 1 month apart). The primary immunogenicity analysis population included 149 booster dose participants in Study 2 (including one individual who had only received a single dose of the primary series) and a random subset of 1055 participants from Study 1 who received two doses (0.5 mL 1 month apart) of Moderna COVID-19 Vaccine. Study 1 and 2 participants included in the analysis population had no serologic or virologic evidence of SARS-CoV-2 infection prior to the first primary series dose and prior to the booster dose, respectively. Among participants assessed for immunogenicity, 60.4% were female, 6.7% were Hispanic or Latino; 95.3% were White, 3.4% were Black or African American, 0.7% were Asian, and 0.7% were American Indian or Alaskan Native; 9.4% were obese (body mass index ≥30 kg/m²). The median age of Study 2 participants was 56 years of age (range 18-82) and 24.8% of participants were 65 years of age and older. Study 2 participants included in the primary immunogenicity analysis population did not have pre-existing medical conditions that would place them at risk of severe COVID-19. Study 1 participants included in the primary immunogenicity analysis population were a stratified random sample which reflected the overall primary efficacy analysis population with regards to demographics and pre-existing medical conditions with a higher percentage of those ≥65 years of age (33.6%), with risk factors for severe COVID-19 (39.4%), and communities of color (53.5%).

Immunogenicity analyses included an assessment of ID50 geometric mean titer (GMT) ratio and difference in seroresponse rates. The analysis of the GMT ratio of ID50 following the booster dose compared to the primary series met the immunobridging criteria for a booster response. Seroresponse for a participant was defined as achieving a ≥4-fold rise in ID50 from baseline (before the booster dose in Study 2 and before the first dose of the primary series in Study 1). The lower limit of the 2-sided 95% CI for the difference in seroresponse rates between Study 1 and Study 2 was -16.7%, which did not meet the immunobridging criterion for a booster response (lower limit of 2-sided 95% CI for the percentage difference of ≥ -10%). These analyses are summarized in Tables 7 and 8.
Table 7: Neutralizing Antibody Geometric Mean Titers (ID50) Against a Pseudovirus Expressing the SARS-CoV-2 Spike Protein (USA_WA1/2020 isolate carrying the D614G mutation) at 28 Days After a Booster Dose in Study 2 vs 28 Days After Completion of the Primary Series in Study 1, Participants ≥18 Years of Age, Per-Protocol Immunogenicity Set*

<table>
<thead>
<tr>
<th>Study 2 Booster Dose</th>
<th>Study 1 Primary Series</th>
<th>GMT Ratio (Study 2/Study 1)</th>
<th>Met Success Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=149</td>
<td>N=1053</td>
<td>1.8 (1.5, 2.1)</td>
<td>Lower limit of 95% CI ≥0.67 Criterion: Yes</td>
</tr>
<tr>
<td>1802 (1548, 2099)</td>
<td>1027 (968, 1089)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Per-Protocol Immunogenicity Set included all subjects who had both baseline (or Study 2 Day 1 for Study 2) and post-vaccination immunogenicity samples, did not have SARS-CoV-2 infection at baseline (or Study 2 Day 1 for Study 2), did not have a major protocol deviation that impacted immune response, and had post-injection immunogenicity assessment at timepoint of primary interest (Day 29 for Study 2 and Day 57 for Study 1).

a Number of subjects with non-missing data at the corresponding timepoint.

b Given the lack of randomization in Study 2, the statistical analysis plan pre-specified an analysis of covariance model for estimating the geometric mean titer that adjusts for differences in age groups (<65 years, ≥65 years).

c Immunobridging is declared if the lower limit of the 2-sided 95% CI for the GMR is >0.67 and the point estimate of the GLSM ratio is ≥1.0.

Note: Antibody values < the lower limit of quantitation (LLOQ) are replaced by 0.5 × LLOQ. Values > the upper limit of quantitation (ULOQ) are replaced by the ULOQ if actual values are not available.

GLSM = Geometric least squares mean

GMR = Geometric mean ratio

Table 8: Seroresponse Rates Against A Pseudovirus Expressing the SARS-CoV-2 Spike Protein (USA_WA1/2020 isolate carrying the D614G mutation) at 28 Days Post-Booster Dose in Study 2 and 28 Days After Completion of the Primary Series in Study 1, Participants ≥18 Years of Age, Per-Protocol Immunogenicity Set*

<table>
<thead>
<tr>
<th>Study 2 Booster Seroresponse*</th>
<th>Study 1 Primary Series Seroresponse*</th>
<th>Difference in Seroresponse Rate (Study 2-Study 1) % (95% CI)d</th>
<th>Met Success Criterion*</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=149</td>
<td>N=1050</td>
<td>-10.5 (-16.7, -6.1)</td>
<td>Lower limit of 95% CI ≥-10% Criterion: No</td>
</tr>
<tr>
<td>131 (87.9) (81.6, 92.7)</td>
<td>1033 (98.4) (97.4, 99.1)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Per-Protocol Immunogenicity Set included all subjects who had both baseline (or Study 2 Day 1 for Study 2) and post-vaccination immunogenicity samples, did not have SARS-CoV-2 infection at baseline (or Study 2 Day 1 for Study 2), did not have a major protocol deviation that impacted immune response, and had post-injection immunogenicity assessment at timepoint of primary interest (Day 29 for Study 2 and Day 57 for Study 1).

a Seroresponse is defined as ≥4-fold rise of pseudovirus neutralizing antibody titers (ID50) from baseline (pre-booster dose in Study 2 and pre-dose 1 in Study 1), where baseline titers < LLOQ are set to LLOQ for the analysis.

b Number of subjects with non-missing data at both baseline and the post-baseline timepoint of interest.

c 95% CI is calculated using the Clopper-Pearson method.

d 95% CI is calculated using the Miettinen-Nurminen (score) confidence limits.

e Immunobridging is declared if the lower limit of the 2-sided 95% CI for the percentage difference is > -10%.
Study 2 participants who met the ≥4-fold increase in titer post-booster dose (87.9%) had a lower baseline GMT of 109 (range of individual titers 9, 4393), whereas Study 2 participants who did not meet the ≥4-fold increase in titers post-booster had a higher baseline GMT of 492 (range of individual titers 162, 2239).

An additional descriptive analysis evaluated seroresponse rates using baseline neutralizing antibody titers prior to dose 1 of the primary series. As shown in Table 9 below, the booster dose seroresponse rate, with seroresponse defined as at least a 4-fold rise relative to the pre-dose 1 titer, was 100%. The difference in seroresponse rates in this post-hoc analysis was 1.6% (95% CI -0.9, 2.6).

Table 9: Analysis of Seroresponse Rates Against a Pseudovirus Expressing the SARS-CoV-2 Spike Protein (USA_WA1/2020 isolate carrying the D614G mutation) at 28 Days Post-Booster Dose in Study 2 and 28 Days After Completion of the Primary Series in Study 1, Participants ≥18 Years of Age, Per-Protocol Immunogenicity Set*

<table>
<thead>
<tr>
<th></th>
<th>Study 2 Booster Seroresponse</th>
<th>Study 1 Primary Series Seroresponse</th>
<th>Difference in Seroresponse Rate (After Booster-After Primary Series)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=148 n (%)</td>
<td>148 (100) (97.5, 100)</td>
<td>1033 (98.4) (97.4, 99.1)</td>
<td>1.6 (-0.9, 2.6)</td>
</tr>
</tbody>
</table>

* Per-Protocol Immunogenicity Set included all subjects who had non-missing data at baseline (before dose 1) and 28 days post-booster in Study 2 or 28 days post-dose 2 in the primary series in Study 1, respectively, did not have SARS-CoV-2 infection at pre-booster in Study 2 or baseline in Study 1, did not have a major protocol deviation that impacted immune response, and had post-injection immunogenicity assessment at timepoint of primary interest.

a Seroresponse is defined as ≥4-fold rise of pseudovirus neutralizing antibody titers (ID50) from pre-dose 1, where baseline titers < LLOQ are set to LLOQ for the analysis.
b Number of subjects with non-missing data at baseline (before dose 1) and 28 days post-booster in Study 2.
c Number of subjects with non-missing data at baseline (before dose 1) and 28 days post-dose 2 in the primary series in Study 1.
d 95% CI is calculated using the Clopper-Pearson method.
e 95% CI is calculated using the Miettinen-Nurminen (score) confidence limits.

18.4 Immunogenicity of a Booster Dose Following Primary Vaccination with Another Authorized or Approved COVID-19 Vaccine

Effectiveness of a Moderna COVID-19 Vaccine (0.25 mL) booster dose in individuals who completed primary vaccination with another authorized or approved COVID-19 Vaccine (heterologous booster dose) is inferred from immunogenicity data supporting effectiveness of a Moderna COVID-19 Vaccine (0.25 mL) booster dose administered following completion of a Moderna COVID-19 Vaccine primary series and from immunogenicity data from an independent Phase 1/2 open-label clinical trial (NCT04889209) conducted in the United States that evaluated a heterologous booster dose (0.5 mL) of the Moderna COVID-19 Vaccine. In this study, adults who had completed primary vaccination with a Moderna COVID-19 Vaccine 2-dose series (N=151), a Janssen COVID-19 Vaccine single dose (N=156), or a Pfizer-BioNTech COVID-19 Vaccine 2-dose series (N=151) at least 12 weeks prior to...
enrollment and who reported no history of SARS-CoV-2 infection were randomized 1:1:1 to receive a booster dose of one of three vaccines: Moderna COVID-19 Vaccine, Janssen COVID-19 Vaccine, or Pfizer-BioNTech COVID-19 Vaccine. Neutralizing antibody titers, as measured by a pseudovirus neutralization assay using a lentivirus expressing the SARS-CoV-2 Spike protein with D614G mutation, were assessed on Day 1 prior to administration of the booster dose and on Day 15 after the booster dose. A booster response to the Moderna COVID-19 Vaccine (0.5 mL) was demonstrated regardless of primary vaccination.

19 HOW SUPPLIED/STORAGE AND HANDLING

Moderna COVID-19 Vaccine Suspension for Intramuscular Injection Multiple-Dose Vials are supplied as follows:

NDC 80777-273-99 Carton of 10 multiple-dose vials, each vial containing 5.5 mL

NDC 80777-273-98 Carton of 10 multiple-dose vials, each vial containing 7.5 mL

During storage, minimize exposure to room light.

Store frozen between -50º to -15ºC (-58º to 5ºF). Store in the original carton to protect from light.

Do not store on dry ice or below -50ºC (-58ºF). Use of dry ice may subject vials to temperatures colder than -50ºC (-58ºF).

Vials may be stored refrigerated between 2º to 8ºC (36º to 46ºF) for up to 30 days prior to first use. Do not refreeze.

Vials may be stored between 8º to 25ºC (46º to 77ºF) for a total of 24 hours.

After the first dose has been withdrawn, the vial should be held between 2º to 25ºC (36º to 77ºF). Vials should be discarded 12 hours after the first puncture.

Thawed vials can be handled in room light conditions.

Do not refreeze once thawed.

Transportation of Thawed Vials at 2º to 8ºC (36º to 46ºF)

If transport at -50º to -15ºC (-58º to 5ºF) is not feasible, available data support transportation of one or more thawed vials for up to 12 hours at 2º to 8ºC (36º to 46ºF) when shipped using shipping containers which have been qualified to maintain 2º to 8ºC (36º to 46ºF) and under routine road and air transport conditions with shaking and vibration minimized. Once thawed and transported at 2º to 8ºC (36º to 46ºF), vials should not be refrozen and should be stored at 2º to 8ºC (36º to 46ºF) until use.
20 PATIENT COUNSELING INFORMATION

Advise the recipient or caregiver to read the Fact Sheet for Recipients and Caregivers.

The vaccination provider must include vaccination information in the state/local jurisdiction’s Immunization Information System (IIS) or other designated system. Advise recipient or caregiver that more information about IISs can be found at: https://www.cdc.gov/vaccines/programs/iis/about.html.

21 CONTACT INFORMATION

For general questions, send an email or call the telephone number provided below.

<table>
<thead>
<tr>
<th>Email</th>
<th>Telephone number</th>
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</thead>
<tbody>
<tr>
<td><a href="mailto:medinfo@modernatx.com">medinfo@modernatx.com</a></td>
<td>1-866-MODERNA</td>
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<tr>
<td></td>
<td>(1-866-663-3762)</td>
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</tbody>
</table>

This EUA Prescribing Information may have been updated. For the most recent Full EUA Prescribing Information, please visit www.modernatx.com/covid19vaccine-eua.

Moderna US, Inc.
Cambridge, MA 02139

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Patent(s): www.modernatx.com/patents
Revised: Oct/20/2021
IMPORTANT PRESCRIBING INFORMATION

Subject: Moderna COVID-19 Vaccine –
Booster Dose Volume (0.25 mL) and Vial Presentation

Dear Vaccination Provider:

Moderna COVID-19 Vaccine is authorized for emergency use to prevent COVID-19 in individuals 18 years of age and older.

A booster dose was authorized on October 20, 2021, for specific populations described below.

The purpose of this letter is to alert vaccination providers that the volume of a booster dose is 0.25 mL.

Primary Vaccination:
Each dose 0.5 mL
A primary series of this vaccine is two 0.5 mL doses administered intramuscularly 1 month apart. A third 0.5 mL primary series dose at least 1 month following the second dose is authorized for administration to individuals at least 18 years of age who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

Booster Vaccination:
One 0.25 mL dose
A booster dose may be administered intramuscularly at least 6 months after completing a primary series with the Moderna COVID-19 Vaccine to individuals:
- 65 years of age and older
- 18 through 64 years of age at high risk of severe COVID-19
- 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2

A single booster dose of the Moderna COVID-19 Vaccine (0.25 mL) may be administered as a heterologous booster dose following completion of primary vaccination with another authorized or approved COVID-19 vaccine. The eligible population(s) and dosing interval for the heterologous booster dose are the same as those authorized for a booster dose of the vaccine used for primary vaccination.

Use of Multidose Vials of Moderna COVID-19 Vaccine
The Moderna COVID-19 Vaccine is supplied in two multiple-dose vial presentations:
- A multiple-dose vial containing 5.5 mL
- A multiple-dose vial containing 7.5 mL

Primary series doses of 0.5 mL and booster doses of 0.25 mL may be extracted from either vial presentation, preferentially using low dead-volume syringes and/or needles.
When extracting only primary series doses, depending on the syringes and needles used, a maximum of 11 doses (range: 10-11 doses) may be extracted from the vial containing 5.5 mL or a maximum of 15 doses (range: 13-15 doses) may be extracted from the vial containing 7.5 mL.

When extracting only booster doses or a combination of primary series and booster doses, the maximum number of doses that may be extracted from either vial presentation should not exceed 20 doses. **Do not puncture the vial stopper more than 20 times.**

If the amount of vaccine remaining in the vial cannot provide a full dose of 0.5 mL or 0.25 mL, discard the vial and contents. Do not pool excess vaccine from multiple vials.

**Vaccine Administration Errors**

Administration of the incorrect volume for any dose is a vaccine administration error. Please report vaccine administration errors to the Vaccine Adverse Event Reporting System (VAERS). See the Fact Sheet for Vaccination Providers for reporting instructions.

**Additional Resources**

To access the most recent Moderna COVID-19 Vaccine Fact Sheets, please scan the QR code or visit the website provided below.

<table>
<thead>
<tr>
<th>Website</th>
<th>Telephone number</th>
</tr>
</thead>
<tbody>
<tr>
<td><a href="https://www.modernatx.com/covid19vaccine-eua">www.modernatx.com/covid19vaccine-eua</a></td>
<td>1-866-MODERNA</td>
</tr>
<tr>
<td></td>
<td>(1-866-663-3762)</td>
</tr>
</tbody>
</table>

Should you have any questions about the use of the Moderna COVID-19 Vaccine, you can either contact the Moderna Medical Information Contact Center at 1 866-MODERNA (1-866-663-3762) or visit www.modernatx.com/covid19vaccine-eua for additional resources.

This letter is not intended as a complete description of the benefits and risks related to the use of Moderna COVID-19 Vaccine. Please refer to the enclosed Fact Sheet.

Sincerely,

Paul Burton

Paul Burton, MD, PhD, FACC, MRCS
Chief Medical Officer, Moderna

*Enclosure: Moderna COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine (Vaccine Providers) and Full Prescribing Information*
Dear Ms. Vinals:

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act or the Act), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes Coronavirus Disease 2019 (COVID-19). On the basis of such determination, the Secretary of HHS on March 27, 2020, declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to Section 564 of the Act (21 U.S.C. 360bbb-3), subject to terms of any authorization issued under that section.


3 In the February 25, 2021 revision, FDA allowed flexibility on the date of submission of monthly periodic safety reports and revised the requirements for reporting of vaccine administration errors by ModernaTX, Inc.

4 In the July 7, 2021 revision, FDA clarified terms and conditions that relate to export of Moderna COVID-19 Vaccine from the United States.

5 In the August 12, 2021 revision, FDA authorized for emergency use a third dose of the Moderna COVID-19 vaccine administered at least 28 days following the two dose regimen of this vaccine in individuals 18 years of age or older who have undergone solid organ transplantation, or individuals 18 years of age or older who have been diagnosed with conditions that are considered to have an equivalent level of immunocompromise.
On October 20, 2021, having concluded that revising this EUA is appropriate to protect the public health or safety under Section 564(g)(2) of the Act, FDA again is reissuing the August 12, 2021 letter of authorization in its entirety with revisions incorporated to authorize for emergency use the administration of a single booster dose of Moderna COVID-19 Vaccine at least 6 months after completing the primary series of this vaccine in individuals: 65 years of age and older; 18 through 64 years of age at high risk of severe COVID-19; and 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2. Additionally, FDA authorizes the administration of a single booster dose of the Moderna COVID-19 Vaccine as a heterologous booster dose following completion of primary vaccination with another authorized or approved COVID-19 vaccine. The eligible population(s) and dosing interval for the heterologous booster dose are the same as those authorized for a booster dose of the vaccine used for primary vaccination.

Moderna COVID-19 Vaccine is for use for active immunization to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older. The vaccine contains a nucleoside-modified messenger RNA encoding the viral spike (S) glycoprotein of SARS-CoV-2 formulated in lipid particles. It is an investigational vaccine not licensed for any indication.

For the December 18, 2020 authorization for individuals 18 years of age and older, FDA reviewed safety and efficacy data from an ongoing phase 3 trial in approximately 30,000 participants randomized 1:1 to receive Moderna COVID-19 Vaccine or saline control. The trial enrolled participants 18 years of age and older. FDA’s review of the available safety data from 30,351 participants 18 years of age and older, who were followed for a median of 7 weeks after receiving the second dose, did not identify specific safety concerns that would preclude issuance of an EUA. Review of additional safety data from these participants with a median of 9 weeks of follow-up after receipt of the second dose did not change FDA’s assessment of safety of the vaccine. FDA’s analysis of the efficacy data from 28,207 participants 18 years of age and older without evidence of SARS-CoV-2 infection prior to dose 1 confirms the vaccine was 94.1% effective (95% confidence interval (CI) 89.3, 96.8) in preventing COVID-19 occurring at least 14 days after the second dose (with 11 COVID-19 cases in the vaccine group compared to 185 COVID-19 cases in the placebo group). In this final scheduled analysis participants had been followed for a median of 9 weeks following the second dose. This result is consistent with that obtained from an interim analysis of efficacy conducted after these participants had been followed for a median of 7 weeks after the second dose (vaccine efficacy 94.5%, 95% CI: 86.5, 97.8). Based on the safety and effectiveness data, and review of manufacturing information regarding product quality and consistency, it is reasonable to believe that Moderna COVID-19 Vaccine may be effective. Additionally, it is reasonable to conclude, based on the totality of the scientific evidence available, that the known and potential benefits of Moderna COVID-19 Vaccine outweigh the known and potential risks of the vaccine, for the prevention of COVID-19 in individuals 18 years of age and older. Finally, on December 17, 2020, the Vaccines and Related Biological Products Advisory Committee voted in agreement with this conclusion.

For the August 12, 2021 authorization of a third primary series dose of the Moderna COVID-19 vaccine in individuals 18 years of age or older who have undergone solid organ transplantation, or individuals 18 years of age or older who are diagnosed with conditions that are considered to
have an equivalent level of immunocompromise, FDA reviewed safety and effectiveness data reported in two manuscripts on solid organ transplant recipients. The first study was a double-blind, randomized-controlled study conducted in 120 individuals who had undergone various solid organ transplant procedures (heart, kidney, kidney-pancreas, liver, lung, pancreas) a median of 3.57 years earlier (range 1.99-6.75 years). A third dose of the Moderna COVID-19 vaccine was administered to 60 individuals approximately 2 months after they had received a second dose (i.e., doses at 0, 1 and 3 months); saline placebo was given to 60 individuals or comparison. The primary outcome was anti-RBD antibody at 4 months greater than 100 U/mL. This titer was selected based on NHP challenge studies as well as a large clinical cohort study to indicate this antibody titer was possibly protective. Secondary outcome was based on a virus neutralization assay polyfunctional T cell responses. Baseline characteristics were comparable between the two study arms as were pre-intervention anti-RBD titer and neutralizing antibodies. Levels of SARS-CoV-2 antibodies indicative of a significant response occurred four weeks after the third dose in 33/60 (55.0%) of the Moderna COVID-19 vaccinated group and 10/57 (17.5%) of the placebo individuals. In the 60 individuals who received a third vaccine dose, the adverse event profile was similar to that after the second dose and no grade 3 or grade 4 adverse events were reported. A supportive secondary study describes a single arm study conducted in 101 individuals who had undergone various solid organ transplant procedures (heart, kidney, liver, lung, pancreas) a median of 97±8 months earlier. A third dose of a similar messenger RNA COVID-19 vaccine, Pfizer-BioNTech COVID-19, was administered to 99 of these individuals approximately 2 months after they had received a second dose. Levels of SARS-CoV-2 antibodies meeting the pre-identified criteria for success occurred four weeks after the third dose in 26/59 (44.0%) of those who were initially considered to be seronegative and received a third dose of the Pfizer-BioNTech COVID-19 vaccine; 67/99 (68%) of the entire group receiving a third vaccination had an increase in antibody titers that the investigators considered significant. In those who received a third vaccine dose, the adverse event profile was similar to that after the second dose and no grade 3 or grade 4 events were reported. Despite the moderate enhancement in antibody titers, the totality of data (including the supportive paper by Kamar et al. and demonstrated efficacy of the product in the elderly and persons with co-morbidities) supports the conclusion that a third dose of the Moderna COVID-19 vaccine may be effective in this population, and that the known and potential benefit of a third dose of Moderna COVID-19 vaccine outweigh the known and potential risks of the vaccine for immunocompromised individuals at least 18 years of age who have received two doses of the Moderna COVID-19 vaccine and who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

For the October 20, 2021 authorization of a single booster dose of the Moderna COVID-19 Vaccine administered at least 6 months after completing the primary series in individuals: 65 years of age or older; 18 through 64 years of age at high risk of severe COVID-19; and 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2, FDA reviewed safety and effectiveness data from an ongoing Phase 2 trial in which 171 participants aged 18 years and older received a single booster dose (0.25 mL) of the Moderna COVID-19 Vaccine at least 6 months (range 5.8-8.5 months) after completion of the primary series (two 0.5 mL doses, one month apart). Following the booster dose, the median follow-up time was 5.7 months. FDA’s review of the currently available safety data did not identify specific safety concerns that would preclude issuance of an EUA. The effectiveness of the
booster dose (0.25 mL) of the Moderna COVID-19 Vaccine is based on an assessment of neutralizing antibody titers (ID50) against a pseudovirus expressing the SARS-CoV-2 Spike protein from a USA_WA1/2020 isolate carrying the D614G mutation. Immunogenicity analyses compared the ID50 one month after the booster dose in 149 participants to the ID50 one month after the primary series in a random subset of 1055 participants from another study. Participants from these two studies had no serologic or virologic evidence of SARS-CoV-2 infection prior to the booster dose and prior to the first primary series dose, respectively. FDA’s analyses confirmed that the immunobridging criteria for a booster response were met for a comparison of the ID50 geometric mean titers and that the immunobridging criterion for a booster response was not met for a comparison of ID50 seroresponse rates. Based on the totality of the scientific evidence available, including data from the above-referenced clinical trials, FDA concluded that a booster dose of the Moderna COVID-19 Vaccine may be effective, and that the known and potential benefits of a single booster dose at least 6 months after completing the primary series outweigh the known and potential risks for individuals 65 years of age and older, individuals 18 through 64 years of age at high risk of severe COVID-19, and individuals 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2.

For the October 20, 2021 authorization of a single booster dose of the Moderna COVID-19 as a heterologous booster dose following completion of primary vaccination with another authorized or approved COVID-19 vaccine, FDA reviewed data from an ongoing Phase1/2 clinical trial in participants 19-85 years of age. In this study, adults who had completed primary vaccination with a Moderna COVID-19 Vaccine 2-dose series (N=151), a Janssen COVID-19 Vaccine single dose (N=156), or a Pfizer-BioNTech COVID-19 Vaccine 2-dose series (N=151) at least 12 weeks prior to enrollment and who reported no history of SARS-CoV-2 infection were randomized 1:1:1 to receive a booster dose of one of three vaccines: Moderna COVID-19 Vaccine (0.5 mL), Janssen COVID-19 Vaccine, or Pfizer-BioNTech COVID-19 Vaccine. Adverse events were assessed through 28 days after the booster dose. An overall review of adverse reactions reported following the Moderna COVID-19 Vaccine heterologous booster dose (0.5 mL) did not identify any new safety concerns, as compared with adverse reactions reported following Moderna COVID-19 Vaccine primary series doses or homologous booster dose (0.25 mL). Neutralizing antibody titers, as measured by a pseudovirus neutralization assay using a lentivirus expressing the SARS-CoV-2 Spike protein with D614G mutation, were assessed on Day 1 prior to administration of the booster dose and on Day 15 after the booster dose. A booster response to the Moderna COVID-19 Vaccine (0.5 mL) was demonstrated regardless of primary vaccination. FDA also considered immunogenicity data from manufacturer-conducted clinical trials that evaluated both a 0.25 mL dose and a 0.5 mL dose of the Moderna COVID-19 Vaccine for the first dose of the primary series and a 0.25 mL dose for a homologous booster dose. Based on the totality of the scientific evidence available, including data from the above-referenced clinical trial, FDA concluded that a heterologous booster dose (0.25 mL) of the Moderna COVID-19 Vaccine may be effective, and that the known and potential benefits of a heterologous booster dose of the Moderna COVID-19 Vaccine following completion of primary vaccination with another authorized or approved COVID-19 vaccine outweigh the known and potential risks.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of Moderna COVID-19 Vaccine for the
prevention of COVID-19, as described in the Scope of Authorization section of this letter (Section II) and subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of Moderna COVID-19 Vaccine for the prevention of COVID-19 when administered as described in the Scope of Authorization (Section II) meets the criteria for issuance of an authorization under Section 564(c) of the Act, because:

A. SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

B. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that Moderna COVID-19 Vaccine may be effective in preventing COVID-19, and that, when used under the conditions described in this authorization, the known and potential benefits of Moderna COVID-19 Vaccine when used to prevent COVID-19 outweigh its known and potential risks; and

C. There is no adequate, approved, and available alternative\(^6\) to the emergency use of Moderna COVID-19 Vaccine to prevent COVID-19.\(^7\)

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited as follows:

\(^6\) Although Comirnaty (COVID-19 Vaccine, mRNA) is approved to prevent COVID-19 in certain individuals within the scope of the Moderna COVID-19 vaccine authorization, there is not sufficient available, approved vaccine, as the approved vaccine is not available for distribution to this population in its entirety at the time of reissuance of this EUA (e.g., due to limitations in supply and/or storage requirements that may impact distribution). Additionally, there are individuals for whom Comirnaty might not be an adequate alternative (e.g., to complete the primary vaccination series for those individuals who have yet to receive their second dose after receiving a first dose of Moderna, or for certain immunocompromised individuals who have received two doses of Moderna but have yet to receive their third dose of the primary series, or for those whom Comirnaty is contraindicated due to allergies to components of the approved product).

\(^7\) No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.
ModernTX, Inc. will supply Moderna COVID-19 Vaccine either directly or through authorized distributor(s)\(^8\) to emergency response stakeholders\(^9\) as directed by the U.S. government, including the Centers for Disease Control and Prevention (CDC) and/or other designee, for use consistent with the terms and conditions of this EUA;

The Moderna COVID-19 Vaccine covered by this authorization will be administered by vaccination providers\(^10\) and used only to prevent COVID-19 in individuals ages 18 and older with a two dose primary regimen (0.5 mL each, one month apart) and to provide:

- a third primary series dose (0.5 mL, at least 28 days following the second dose of the two dose primary regimen) to individuals 18 years of age and older who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise;
- a single booster dose (0.25 mL) administered at least 6 months after completion of a primary series of the vaccine to individuals; 65 years of age or older; 18 through 64 years of age at high risk of severe COVID-19; and 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2; and

\(^8\) “Authorized Distributor(s)” are identified by ModernaTX, Inc. or, if applicable, by a U.S. government entity, such as the Centers for Disease Control and Prevention (CDC) and/or other designee, as an entity or entities allowed to distribute authorized Moderna COVID-19 Vaccine.

\(^9\) For purposes of this letter, “emergency response stakeholder” refers to a public health agency and its delegates that have legal responsibility and authority for responding to an incident, based on political or geographical boundary lines (e.g., city, county, tribal, territorial, State, or Federal), or functional (e.g., law enforcement or public health range) or sphere of authority to administer, deliver, or distribute vaccine in an emergency situation. In some cases (e.g., depending on a state or local jurisdiction’s COVID-19 vaccination response organization and plans), there might be overlapping roles and responsibilities among “emergency response stakeholders” and “vaccination providers” (e.g., if a local health department is administering COVID-19 vaccines; if a pharmacy is acting in an official capacity under the authority of the state health department to administer COVID-19 vaccines). In such cases, it is expected that the conditions of authorization that apply to emergency response stakeholders and vaccination providers will all be met.

\(^10\) For purposes of this letter, “vaccination provider” refers to the facility, organization, or healthcare provider licensed or otherwise authorized by the emergency response stakeholder (e.g., non-physician healthcare professionals, such as nurses and pharmacists pursuant to state law under a standing order issued by the state health officer) to administer or provide vaccination services in accordance with the applicable emergency response stakeholder’s official COVID-19 vaccination and emergency response plan(s) and who is enrolled in the CDC COVID-19 Vaccination Program. If the vaccine is exported from the United States, a “vaccination provider” is a provider that is authorized to administer this vaccine in accordance with the laws of the country in which it is administered. For purposes of this letter, “healthcare provider” also refers to a person authorized by the U.S. Department of Health and Human Services (e.g., under the PREP Act Declaration for Medical Countermeasures against COVID-19) to administer FDA-authorized COVID-19 vaccine (e.g., qualified pharmacy technicians and State-authorized pharmacy interns acting under the supervision of a qualified pharmacist). See, e.g., HHS. Fourth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration. 85 FR 79190 (December 9, 2020).
a single booster dose (0.25 mL) administered as a heterologous booster dose following completion of primary vaccination with another authorized or approved COVID-19 vaccine, where the eligible population(s) and dosing interval for the heterologous booster dose are the same as those authorized for a booster dose of the vaccine used for primary vaccination.

- The Moderna COVID-19 Vaccine may be administered by a vaccination provider without an individual prescription for each vaccine recipient.

**Product Description**

The Moderna COVID-19 Vaccine is supplied as a frozen suspension in multiple dose vials. The Moderna COVID-19 Vaccine does not contain a preservative.

Each 0.5 mL dose of the Moderna COVID-19 Vaccine contains 100 mcg of a nucleoside-modified messenger RNA encoding the viral spike (S) glycoprotein of SARS-CoV-2. Each dose of the Moderna COVID-19 Vaccine also includes the following ingredients: lipids (SM-102; 1,2-dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 [PEG2000-DMG]; cholesterol; and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate, and sucrose.

A single booster dose of Moderna COVID-19 Vaccine is 0.25 mL.

The manufacture of the authorized Moderna COVID-19 Vaccine is limited to those facilities identified and agreed upon in the ModernaTX, Inc. request for authorization.

The Moderna COVID-19 Vaccine vial label and carton labels are clearly marked for “Emergency Use Authorization.” The Moderna COVID-19 Vaccine is authorized to be distributed, stored, further redistributed, and administered by emergency response stakeholders when packaged in the authorized manufacturer packaging (i.e., vials and cartons), despite the fact that the vial and carton labels may not contain information that otherwise would be required under the FD&C Act.

The Moderna COVID-19 Vaccine is authorized for emergency use with the following product-specific information required to be made available to vaccination providers and recipients, respectively (referred to as “authorized labeling”):

- Fact Sheet for Recipients and Caregivers: Emergency Use Authorization (EUA) of the Moderna COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) in Individuals 18 Years of Age and Older

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of Moderna COVID-19 Vaccine, when used to prevent
COVID-19 and used in accordance with this Scope of Authorization (Section II), outweigh its known and potential risks.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that Moderna COVID-19 Vaccine may be effective in preventing COVID-19 when used in accordance with this Scope of Authorization (Section II), pursuant to Section 564(c)(2)(A) of the Act.

Having reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, I have concluded that Moderna COVID-19 Vaccine (as described in this Scope of Authorization (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of Moderna COVID-19 Vaccine under this EUA must be consistent with, and may not exceed, the terms of the Authorization, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section III). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS’s determination under Section 564(b)(1)(C) described above and the Secretary of HHS’s corresponding declaration under Section 564(b)(1), Moderna COVID-19 Vaccine is authorized to prevent COVID-19 in individuals 18 years of age and older as described in the Scope of Authorization (Section II) under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

III. Conditions of Authorization

Pursuant to Section 564 of the Act, I am establishing the following conditions on this authorization:

**ModernaTX, Inc. and Authorized Distributor(s)**

A. ModernaTX, Inc. and authorized distributor(s) will ensure that the authorized Moderna COVID-19 Vaccine is distributed, as directed by the U.S. government, including CDC and/or other designee, and the authorized labeling (i.e., Fact Sheets) will be made available to vaccination providers, recipients, and caregivers consistent with the terms of this letter.

B. ModernaTX, Inc. and authorized distributor(s) will ensure that appropriate storage and cold chain is maintained until delivered to emergency response stakeholders’ receipt sites.

C. ModernaTX, Inc. will ensure that the terms of this EUA are made available to all relevant stakeholders (e.g., emergency response stakeholders, authorized distributors, and vaccination providers) involved in distributing or receiving authorized Moderna COVID-19 Vaccine. ModernaTX, Inc. will provide to all relevant stakeholders a copy of this letter of authorization and communicate any subsequent amendments that might be made to this letter of authorization and its authorized labeling.
D. ModernaTX, Inc. may develop and disseminate instructional and educational materials (e.g., video regarding vaccine handling, storage/cold-chain management, preparation, disposal) that are consistent with the authorized emergency use of the vaccine as described in the letter of authorization and authorized labeling, without FDA’s review and concurrence, when necessary to meet public health needs during an emergency. Any instructional and educational materials that are inconsistent with the authorized labeling are prohibited.

E. ModernaTX, Inc. may request changes to this authorization, including to the authorized Fact Sheets for Moderna COVID-19 Vaccine. Any request for changes to this EUA must be submitted to Office of Vaccines Research and Review (OVRR)/Center for Biologics Evaluation and Research (CBER). Such changes require appropriate authorization prior to implementation.11

F. ModernaTX, Inc. will report to Vaccine Adverse Event Reporting System (VAERS):
   - Serious adverse events (irrespective of attribution to vaccination);
   - Cases of Multisystem Inflammatory Syndrome in adults; and
   - Cases of COVID-19 that result in hospitalization or death, that are reported to ModernaTX, Inc.

These reports should be submitted to VAERS as soon as possible but no later than 15 calendar days from initial receipt of the information by ModernaTX, Inc.

G. ModernaTX, Inc. must submit to Investigational New Drug application (IND) number 19745 periodic safety reports at monthly intervals, in accordance with a due date agreed upon with the Office of Biostatistics and Epidemiology (OBE) beginning after the first full calendar month after authorization. Each periodic safety report is required to contain descriptive information which includes:
   - A narrative summary and analysis of adverse events submitted during the reporting interval, including interval and cumulative counts by age groups, special populations (e.g., pregnant women), and adverse events of special interest;
   - A narrative summary and analysis of vaccine administration errors, whether or not associated with an adverse event, that were identified since the last reporting interval;
   - Newly identified safety concerns in the interval; and

11 The following types of revisions may be authorized without reissuing this letter: (1) changes to the authorized labeling; (2) non-substantive editorial corrections to this letter; (3) new types of authorized labeling, including new fact sheets; (4) new carton/container labels; (5) expiration dating extensions; (6) changes to manufacturing processes, including tests or other authorized components of manufacturing; (7) new conditions of authorization to require data collection or study. For changes to the authorization, including the authorized labeling, of the type listed in (3), (6), or (7), review and concurrence is required from the Preparedness and Response Team (PREP)/Office of the Center Director (OD)/CBER and the Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS).
• Actions taken since the last report because of adverse experiences (for example, changes made to Healthcare Providers Administering Vaccine (Vaccination Providers) Fact Sheet, changes made to studies or studies initiated).

H. No changes will be implemented to the description of the product, manufacturing process, facilities, or equipment without notification to and concurrence by FDA.

I. All manufacturing facilities will comply with Current Good Manufacturing Practice requirements.

J. ModernaTX, Inc. will submit to the EUA file Certificates of Analysis (CoA) for each drug product lot at least 48 hours prior to vaccine distribution. The CoA will include the established specifications and specific results for each quality control test performed on the final drug product lot.

K. ModernaTX, Inc. will submit to the EUA file quarterly manufacturing reports, starting in July 2021, that include a listing of all Drug Substance and Drug Product lots produced after issuance of this authorization. This report must include lot number, manufacturing site, date of manufacture, and lot disposition, including those lots that were quarantined for investigation or those lots that were rejected. Information on the reasons for lot quarantine or rejection must be included in the report.

L. ModernaTX, Inc. and authorized distributor(s) will maintain records regarding release of Moderna COVID-19 Vaccine for distribution (i.e., lot numbers, quantity, release date).

M. ModernaTX, Inc. and authorized distributor(s) will make available to FDA upon request any records maintained in connection with this EUA.

N. ModernaTX, Inc. will conduct post-authorization observational studies to evaluate the association between Moderna COVID-19 Vaccine and a pre-specified list of adverse events of special interest, including myocarditis and pericarditis, along with deaths and hospitalizations, and severe COVID-19. The study population should include individuals administered the authorized Moderna COVID-19 Vaccine under this EUA in the general U.S. population (18 years of age and older), individuals who receive a booster dose, populations of interest such as healthcare workers, pregnant women, immunocompromised individuals, subpopulations with specific comorbidities. The studies should be conducted in large scale databases with an active comparator. ModernaTX, Inc. will provide protocols and status update reports to the IND 19745 with agreed-upon study designs and milestone dates.

O. ModernaTX, Inc., working with its contract research organization, will continue to monitor the performance of its clinical investigators in ongoing clinical studies of its vaccine and will report to FDA promptly any significant deviations from the protocols.
Emergency Response Stakeholders

P. Emergency response stakeholders will identify vaccination sites to receive authorized Moderna COVID-19 Vaccine and ensure its distribution and administration, consistent with the terms of this letter and CDC’s COVID-19 Vaccination Program.

Q. Emergency response stakeholders will ensure that vaccination providers within their jurisdictions are aware of this letter of authorization, and the terms herein and any subsequent amendments that might be made to the letter of authorization, instruct them about the means through which they are to obtain and administer the vaccine under the EUA, and ensure that the authorized labeling [i.e., Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Fact Sheet for Recipients and Caregivers] is made available to vaccination providers through appropriate means (e.g., e-mail, website).

R. Emergency response stakeholders receiving authorized Moderna COVID-19 Vaccine will ensure that appropriate storage and cold chain is maintained.

Vaccination Providers

S. Vaccination providers will administer the vaccine in accordance with the authorization and will participate and comply with the terms and training required by CDC’s COVID-19 Vaccination Program.

T. Vaccination providers will provide the Fact Sheet for Recipients and Caregivers to each individual receiving vaccination and provide the necessary information for receiving their second dose.

U. Vaccination providers administering Moderna COVID-19 Vaccine must report the following information associated with the administration of Moderna COVID-19 Vaccine of which they become aware to VAERS in accordance with the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers):
- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events (irrespective of attribution to vaccination)
- Cases of Multisystem Inflammatory Syndrome in adults
- Cases of COVID-19 that result in hospitalization or death

Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html. The VAERS reports should include the words “Moderna COVID-19 Vaccine EUA” in the description section of the report. More information is available at vaers.hhs.gov or by calling 1-800-822-7967. To the extent feasible, report to ModernaTX, Inc., by contacting 1-866-663-3762, by providing a copy of the VAERS form to ModernaTX, Inc., Fax: 1-866-599-1342 or by email; ModernaPV@modernatx.com.
V. Vaccination providers will conduct any follow-up requested by the U.S government, including CDC, FDA, or other designee, regarding adverse events to the extent feasible given the emergency circumstances.

W. Vaccination providers will monitor and comply with CDC and/or emergency response stakeholder vaccine management requirements (e.g., requirements concerning obtaining, tracking, and handling vaccine) and with requirements concerning reporting of vaccine administration data to CDC.

X. Vaccination providers will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to CDC and FDA for inspection upon request.

Conditions Related to Printed Matter, Advertising, and Promotion

Y. All descriptive printed matter, advertising, and promotional material relating to the use of the Moderna COVID-19 Vaccine shall be consistent with the authorized labeling, as well as the terms set forth in this EUA, and meet the requirements set forth in Section 502(a) and (n) of the FD&C Act and FDA implementing regulations.

Z. All descriptive printed matter, advertising, and promotional material relating to the use of the Moderna COVID-19 Vaccine clearly and conspicuously shall state that:

- This product has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 18 years of age and older; and
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

Condition Related to Export

AA. If the product is exported from the United States, conditions C, D, and P through Z do not apply, but export is permitted only if 1) the regulatory authorities of the country in which the vaccine will be used are fully informed that this vaccine is subject to an EUA and is not approved or licensed by FDA and 2) the intended use of the vaccine will comply in all respects with the laws of the country in which the product will be used. The requirement in this letter that the authorized labeling (i.e., Fact Sheets) be made available to vaccination providers, recipients, and caregivers in condition A will not apply if the authorized labeling (i.e., Fact Sheets) are made available to the regulatory authorities of the country in which the vaccine will be used.
IV. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

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Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration