



January 31, 2022

ModernaTX, Inc.  
Attention: Ms. Michelle Olsen  
200 Technology Square  
Cambridge, MA 02139

Dear Ms. Olsen:

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).<sup>1</sup> 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.<sup>2</sup>

On December 19, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of Moderna COVID-19 Vaccine for the prevention of COVID-19 for individuals 18 years of age and older, pursuant to Section 564 of the Act. FDA reissued the letter of authorization on: February 25, 2021,<sup>3</sup> July 7, 2021,<sup>4</sup> August 12, 2021,<sup>5</sup>

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<sup>1</sup> U.S. Department of Health and Human Services, Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3. February 4, 2020.

<sup>2</sup> U.S. Department of Health and Human Services, Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3, 85 FR 18250 (April 1, 2020).

<sup>3</sup> 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.

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

<sup>5</sup> In the August 12, 2021 revision, FDA authorized for emergency use a third dose of the Moderna COVID-19 vaccine administered at least 1 month following the two dose regimen of this vaccine in individuals 18 years of age

October 20, 2021,<sup>6</sup> November 19, 2021,<sup>7</sup> and January 7, 2022.<sup>8</sup>

On January 31, 2021, FDA approved the biologics license application (BLA) submitted by ModernaTX, Inc. for SPIKEVAX (COVID-19 Vaccine, mRNA) for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older.

On January 31, 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 is reissuing the January 7, 2022 letter of authorization in its entirety with revisions incorporated to clarify that the EUA will remain in place for the Moderna COVID-19 Vaccine for the previously-authorized indication and uses, and to authorize the use of SPIKEVAX (COVID-19 Vaccine, mRNA) under this EUA for certain uses that are not included in the approved BLA. In addition, FDA is revising the Fact Sheet for Recipients and Caregivers as the Vaccine Information Fact Sheet for Recipients and Caregivers, which comprises the Fact Sheet for the authorized Moderna COVID-19 Vaccine and information about the FDA-licensed vaccine, SPIKEVAX (COVID-19 Vaccine, mRNA), as well as the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers).

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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.

<sup>6</sup> In the October 20, 2021 revision, FDA authorized 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 authorized 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 were the same as those authorized for a booster dose of the vaccine used for primary vaccination.

<sup>7</sup> In the November 19, 2021 revision, FDA authorized the use of Moderna COVID-19 Vaccine as a single booster dose in individuals 18 years of age or older at least 6 months after completing the primary series of this vaccine (i.e., as a homologous booster dose), and authorized the use of the vaccine as a single booster dose following completion of primary vaccination with another authorized or approved COVID-19 vaccine (i.e., as a heterologous booster dose) in individuals 18 years of age or older. The dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination.

<sup>8</sup> In the January 7, 2022 revision, FDA revised the authorized dosing interval of the homologous booster dose to at least five (5) months after completion of the primary series of this vaccine. In addition, FDA revised the Fact Sheets for Healthcare Providers Administering Vaccine (Vaccination Providers) and the Fact Sheet for Recipients and Caregivers to reflect this revision.

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. SPIKEVAX (COVID-19 Vaccine, mRNA) is the same formulation as the Moderna COVID-19 Vaccine and can be used interchangeably with the Moderna COVID-19 Vaccine to provide the COVID-19 vaccination series.<sup>9</sup>

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

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<sup>9</sup> The licensed vaccine has the same formulation as the EUA-authorized vaccine and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns. The products are legally distinct with certain differences that do not impact safety or effectiveness.

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 for 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  $97 \pm 8$  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 50 µg 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 100 µg 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 50 µg booster dose (0.25 mL) of the Moderna COVID-19 Vaccine is based on an assessment of neutralizing antibody titers (ID<sub>50</sub>) 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 Phase 1/2 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 100 µg (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.

For the November 19, 2021 authorization expanding the eligible population for the homologous and heterologous booster doses to individuals 18 years of age and older, FDA reviewed data

provided by the sponsor and other data available to FDA, including real world evidence. Data previously reviewed to support the October 20, 2021, authorization of a homologous booster dose, together with new real-world data indicating increasing COVID-19 cases in the United States, including among vaccinated individuals, and suggesting a decreased risk of myocarditis following mRNA COVID-19 vaccine booster doses compared with second primary series doses, supported expansion of the population eligible for a Moderna COVID-19 vaccine homologous booster dose to include all individuals 18 years of age and older who completed the primary series at least 6 months previously. Data previously reviewed to support the October 20, 2021, authorization of a heterologous booster dose, together with data and information to support authorization of the EUA amendment to expand the eligible population for a homologous booster dose of the Pfizer-BioNTech Vaccine, support a revision to the Moderna COVID-19 Vaccine EUA such that the eligible population for a heterologous booster dose of the Moderna COVID-19 Vaccine is all adults 18 years of age and older who completed primary vaccination with another authorized or approved COVID-19 vaccine. Based on the totality of the scientific evidence available, FDA concluded that a homologous or heterologous booster dose of the Moderna COVID-19 Vaccine may be effective, and that the known and potential benefits of the booster dose of the Moderna COVID-19 Vaccine following completion of primary vaccination with Moderna COVID-19 Vaccine or another authorized or approved COVID-19 vaccine outweigh the known and potential risks in individuals 18 years of age and older.

For the January 7, 2022 authorization revising the authorized dosing interval of the homologous booster dose to at least 5 months after completion of the primary series, the FDA reviewed: prepublications; accepted publications; published publications; and real world evidence on the safety of booster doses provided by the Israeli Ministry of Health, which includes data from approximately 4.1 million third (booster) doses of the Pfizer-BioNTech COVID-19 Vaccine given to individuals 16 years of age and older at least 5 months after the primary series, and which did not raise new safety concerns associated with the booster dose. Although the overall composition of the Moderna COVID-19 Vaccine is different than the Pfizer-BioNTech COVID-19 vaccine, both are mRNA vaccines with safety and efficacy profiles that, though not identical, are relatively similar. Acknowledging the differences, it is reasonable to make the inference that the safety data on the 5 month interval for booster doses obtained in the population in Israel can apply to the Moderna COVID-19 Vaccine. Based on the totality of the scientific evidence available, FDA concludes that a homologous booster dose of the Moderna COVID-19 Vaccine may be effective and that the known and potential benefits of the booster dose of the Moderna COVID-19 Vaccine following completion of primary vaccination with the Moderna COVID-19 Vaccine outweigh the known and potential risks in individuals 18 years of age and older when given at least 5 months following the primary series.

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. Additionally, as specified in subsection III.CC., I am authorizing use of SPIKEVAX (COVID-19 Vaccine, mRNA) under this EUA as described in the Scope of Authorization section of this letter (Section II).

## **I. Criteria for Issuance of Authorization**

I have concluded that the emergency use of Moderna COVID-19 Vaccine<sup>10</sup> 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<sup>11</sup> to the emergency use of Moderna COVID-19 Vaccine to prevent COVID-19.<sup>12</sup>

## **II. Scope of Authorization**

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<sup>10</sup> In this section (Section I), references to Moderna COVID-19 Vaccine also apply to SPIKEVAX (COVID-19 Vaccine, mRNA).

<sup>11</sup> Although SPIKEVAX (COVID-19 Vaccine, mRNA) and Comirnaty (COVID-19 Vaccine, mRNA) are approved to prevent COVID-19 in certain individuals within the scope of the Moderna COVID-19 Vaccine authorization, there is not sufficient approved vaccine available for distribution to this population in its entirety at the time of reissuance of this EUA. Additionally, there are no COVID-19 vaccines that are approved to provide: a third primary series dose to certain immunocompromised populations described in this EUA; a homologous booster dose to the authorized population described in this EUA; or a heterologous booster dose following completion of primary vaccination with another authorized or approved COVID-19 vaccine.

<sup>12</sup> No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

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

- ModernaTX, Inc. will supply Moderna COVID-19 Vaccine either directly or through authorized distributor(s)<sup>13</sup> to emergency response stakeholders<sup>14</sup> 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 may be administered by a vaccination provider<sup>15</sup> without an individual prescription for each vaccine recipient.
- The Moderna COVID-19 Vaccine covered by this authorization will be administered by vaccination providers 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 1 month following the second dose of the two dose primary regimen) to individuals 18 years of age and

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<sup>13</sup> “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.

<sup>14</sup> 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.

<sup>15</sup> 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).



- 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 5 months after completion of a primary series of the vaccine to individuals 18 years of age and older; and
  - 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 in individuals 18 years of age and older, where the dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination.

This authorization also covers the use of the licensed SPIKEVAX (COVID-19 Vaccine, mRNA) product when used to provide: (1) a third primary series dose (0.5 mL) at least 1 month following the second dose to individuals 18 years of age or older who have undergone solid organ transplantation or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise; (2) a single homologous booster dose (0.25 mL) at least 5 months after completion of the primary series to individuals 18 years of age or older; and (3) a single booster dose as a heterologous booster dose (0.25 mL) following completion of primary vaccination with another authorized or approved COVID-19 vaccine in individuals 18 years of age and older, where the dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination.

Therefore, for individuals 18 years of age and older, SPIKEVAX (COVID-19 Vaccine, mRNA) is authorized to complete the primary regimen or provide a booster dose for individuals who received their initial primary dose(s) with the Moderna COVID-19 Vaccine, and the Moderna COVID-19 Vaccine is authorized to complete the primary regimen or provide a booster for individuals who received their initial primary dose(s) with SPIKEVAX (COVID-19 Vaccine, mRNA).

### **Product Description<sup>16</sup>**

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

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<sup>16</sup> For SPIKEVAX (COVID-19 Vaccine, mRNA) product description, please see the SPIKEVAX (COVID-19 Vaccine, mRNA) prescribing information, found here: <https://www.fda.gov/media/155675/download>.

1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate, and sucrose in sterile water for injection.

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 Healthcare Providers Administering Vaccine (Vaccination Providers): Emergency Use Authorization (EUA) of the Moderna COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19)
- Vaccine Information Fact Sheet for Recipients and Caregivers About SPIKEVAX (COVID-19 Vaccine, mRNA) and 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,<sup>17</sup> 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.

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<sup>17</sup> The conclusions supporting authorization stated in this section (Section II) also apply to SPIKEVAX (COVID-19 Vaccine, mRNA).

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

(OVR)/Center for Biologics Evaluation and Research (CBER). Such changes require appropriate authorization prior to implementation.<sup>18</sup>

- 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
  - 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.

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<sup>18</sup> 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).

- 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 Vaccine Information 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 Vaccine Information Fact Sheet for Recipients and Caregivers to each individual receiving vaccination and provide the necessary information for receiving their second dose and/or third dose.
- U. Vaccination providers administering the vaccine must report the following information associated with the administration of the 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](https://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.

#### Conditions With Respect to Use of Licensed Product

- BB. SPIKEVAX (COVID-19 Vaccine, mRNA) is licensed for individuals 18 years of age and older. There remains, however, a significant amount of Moderna COVID-19 Vaccine that was manufactured and labeled in accordance with this emergency use authorization. This authorization remains in place for Moderna COVID-19 Vaccine for this population.

CC. This authorization also covers the use of the licensed SPIKEVAX (COVID-19 Vaccine, mRNA) product when used to provide: (1) a third primary series dose (0.5 mL) to individuals 18 years of age or older who have undergone solid organ transplantation or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise; (2) a single homologous booster dose (0.25 mL) after completing the primary series to individuals 18 years of age or older; and (3) a heterologous booster dose (0.25 mL) in individuals 18 years of age and older who have completed primary vaccination with a different authorized or approved COVID-19 vaccine as described in the Scope of Authorization (Section II) under this EUA. Conditions A through X in this letter apply when SPIKEVAX (COVID-19 Vaccine, mRNA) is provided for the uses described in this subsection III.CC., except that product manufactured and labeled in accordance with the approved BLA is deemed to satisfy the manufacturing, labeling, and distribution requirements of this authorization.

#### **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