vaccination or receipt of the most recent booster dose with any FDA authorized or approved monovalent COVID-19 vaccine.[20]

The December 8, 2022 authorization of a booster dose of Moderna COVID-19 Vaccine, Bivalent in individuals 6 months through 5 years of age is based on data that FDA relied on for the August 31, 2022 authorization of the Moderna COVID-19 Vaccine, Bivalent in individuals 18 years of age and older. In addition, FDA reviewed postmarketing safety data with Moderna COVID-19 Vaccine and Moderna COVID-19 Vaccine, Bivalent, and safety and immunogenicity data regarding the use of the monovalent Moderna COVID-19 Vaccine as a booster dose in individuals 17 months through 5 years of age collected in Study 4. Study 4 is an ongoing Phase 2/3 Study with multiple parts. The open-label booster portion of the study involved 145 participants 17 months through 5 years of age who received a booster dose of Moderna COVID-19 Vaccine (10 mcg mRNA) at least 6 months after the completion of the Moderna COVID-19 Vaccine two-dose primary series. As of the data cutoff date of August 18, 2022, the median duration of follow-up for safety after the booster dose was 99 days. The primary immunogenicity analysis population included 56 booster dose participants in Study 4 and a random subset of 295 participants 18 through 25 years from Study 1 who had completed primary vaccination with two doses of Moderna COVID-19 Vaccine (100 mcg mRNA per dose) 1 month apart. Study 1 and 4 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. The primary immunogenicity analyses of the GMC ratio and difference in seroresponse rates following the booster dose in Study 4 compared to following the primary series in Study 1 met the pre-defined immunobridging success criteria. Seroresponse for a participant was defined as achieving a ≥4-fold rise of neutralizing antibody concentration from baseline (before the first dose of the primary series in Study 4 and Study 1). In a descriptive analysis, the booster dose seroresponse rate among participants 17 months through 5 years of age with seroresponse defined as at least a 4-fold rise relative to the pre-booster concentration, was 94.6%. The difference in seroresponse rates (Study 4 participants minus Study 1 participants) in this post-hoc analysis was -4.7% (95% CI -14.0, -0.9). Based on the totality of the scientific evidence available, FDA concluded that it is reasonable to believe that Moderna COVID-19 Vaccine, Bivalent may be effective as a booster dose in individuals 6 months through 5 years of age when administered at least 2 months after completion of primary vaccination with Moderna COVID-19 Vaccine. Additionally, FDA determined 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, Bivalent outweigh the known and potential risks of the vaccine for the prevention of COVID-19 in individuals 6 months through 5 years of age when administered at least 2 months after completion of primary vaccination with Moderna COVID-19 Vaccine.

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 and Moderna COVID-19 Vaccine, Bivalent for the prevention of COVID-19, as described in the Scope of

Authorization section (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 (Section II).

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of Moderna COVID-19 Vaccine[21] 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[22] to the emergency use of Moderna COVID-19 Vaccine to prevent COVID-19.[23]

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:

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[21] In this section (Section I), references to Moderna COVID-19 Vaccine also apply to SPIKEVAX (COVID-19 Vaccine, mRNA) and Moderna COVID-19 Vaccine, Bivalent.

[22] Although SPIKEVAX (COVID-19 Vaccine, mRNA) and Comirnaty (COVID-19 Vaccine, mRNA) are approved to prevent COVID-19 in certain individuals who fall 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 or COVID-19 vaccination in individuals younger than 12 years of age. In addition, there are no bivalent vaccines that contain or encode the spike protein of the Omicron variant of SARS-CoV-2 that are approved to prevent COVID-19.

[23] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

Therefore, for individuals 12 years of age and older, SPIKEVAX (COVID-19 Vaccine, mRNA) is authorized to complete the primary series for individuals who received their initial primary dose with the Moderna COVID-19 Vaccine supplied in multiple-dose vials with red caps and light blue borders, and the Moderna COVID-19 Vaccine supplied in vials with red caps and light blue borders is authorized to complete the primary series for individuals who received their initial primary dose with SPIKEVAX (COVID-19 Vaccine, mRNA).

Product Description[27]

The Moderna COVID-19 Vaccine, supplied as a frozen suspension is provided in four different color-coded multiple dose vials:

Multiple dose vials with red caps and labels with light blue borders

Each 0.5 mL primary series dose of the Moderna COVID-19 Vaccine contains 100 mcg of a mRNA encoding the pre-fusion stabilized Spike glycoprotein (S) of SARS-CoV-2 Wuhan-Hu-1 strain (Original). Each 0.5 mL dose of the Moderna COVID-19 Vaccine also includes 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]), 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 in Sterile Water for Injection. The Moderna COVID-19 Vaccine does not contain a preservative.

Multiple dose vials with dark blue caps and labels with purple borders

Each 0.5 mL primary series dose of Moderna COVID-19 Vaccine contains 50 mcg of mRNA encoding the pre-fusion stabilized Spike glycoprotein (S) of SARS-CoV-2 Wuhan-Hu-1 strain (Original). Each 0.5 mL dose of the Moderna COVID-19 Vaccine also contains the following ingredients: a total lipid content of 1.01 mg (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), 0.25 mg tromethamine, 1.2 mg tromethamine hydrochloride, 0.021 mg acetic acid, 0.10 mg sodium acetate trihydrate, and 43.5 mg sucrose in Sterile Water for Injection. The Moderna COVID-19 Vaccine does not contain a preservative.

Multiple dose vials with dark blue caps and labels with teal borders

Each 0.5 mL primary series dose of Moderna COVID-19 Vaccine contains 50 mcg of mRNA encoding the pre-fusion stabilized Spike glycoprotein (S) of SARS-CoV-2

[27] 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.

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 and Moderna COVID-19 Vaccine, Bivalent are 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 and Moderna COVID-19 Vaccine, Bivalent. 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 vaccines 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 and Moderna COVID-19 Vaccine, Bivalent. 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.[29]

F. ModernaTX, Inc. will report to Vaccine Adverse Event Reporting System (VAERS):
- Serious adverse events (irrespective of attribution to vaccination);
- Cases of myocarditis;
- Cases of pericarditis;
- Cases of Multisystem Inflammatory Syndrome in children and 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 monthly, in accordance with a due date agreed upon with the Office of Biostatistics and Pharmacovigilance (OBPV)/CBER 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).

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[29] 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. All changes to the authorization require review and concurrence from OVRR. 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).

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" or "Moderna COVID-19 Vaccine, Bivalent EUA," as appropriate, 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 and Moderna COVID-19 Vaccine, Bivalent 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 or Moderna COVID-19 Vaccine, Bivalent clearly and conspicuously shall state, as applicable, that:

- The Moderna COVID-19 Vaccine 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 12 years of age and older, 6 years through 11 years of age, or 6 months through 5 years of age as appropriate; or
- The Moderna COVID-19 Vaccine, Bivalent 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 12 years of age and older, 6 years through 11 years of age, or 6 months through 5 years of age as appropriate; and