

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at <https://www.regulations.gov>, <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>.

Dated: August 22, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–18517 Filed 8–26–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0895]

Notice of Approval of Product Under Voucher: Material Threat Medical Countermeasure Priority Review Voucher

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the approval of a product redeeming a priority review voucher. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the 21st Century Cures Act, authorizes FDA to award priority review vouchers to sponsors of a material threat medical countermeasure application that meets certain criteria upon approval of such application. FDA is required to publish notice of the issuance of priority review vouchers as well as the approval of products redeeming a priority review voucher. FDA has determined that the application for MOUNJARO (tirzepatide) injection, approved May 13, 2022, meets the redemption criteria.

FOR FURTHER INFORMATION CONTACT: Elizabeth Sadove, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–8515 (this is not a toll-free number), email: EUA.OCEt@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under section 565A of the FD&C Act (21 U.S.C. 360bbb–4a), which was added by section 3086 of the 21st Century Cures Act (Pub. L. 114–255), FDA will report the issuance of material threat medical

countermeasure priority review vouchers and the approval of products for which a voucher was redeemed. FDA has determined that the application for MOUNJARO (tirzepatide) injection, approved May 13, 2022, meets the redemption criteria.

For further information about the Material Threat Medical Countermeasure Priority Review Voucher Program and for a link to the full text of section 565A of the FD&C Act, go to <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/21st-century-cures-act-mcm-related-cures-provisions>. For further information about MOUNJARO (tirzepatide) injection, go to the “Drugs@FDA” website at <https://www.accessdata.fda.gov/scripts/cder/daf/>.

Dated: August 23, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–18523 Filed 8–26–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0335]

Authorization of Emergency Use of a Biological Product During the COVID–19 Pandemic; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of an Emergency Use Authorization (EUA) (the Authorization) under the Federal Food, Drug, and Cosmetic Act (FD&C Act) for use during the COVID–19 pandemic. FDA has issued one Authorization for a biological product as requested by Novavax, Inc. The Authorization contains, among other things, conditions on the emergency use of the authorized product. The Authorization follows the February 4, 2020, determination by the Secretary of Health and Human Services (HHS) that there is a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves a novel (new) coronavirus. The virus, now named SARS–CoV–2, causes the illness COVID–19. On the basis of such determination, the Secretary of HHS declared on March 27, 2020, that

circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID–19 pandemic, pursuant to the FD&C Act, subject to the terms of any authorization issued under that section. The Authorization, which includes an explanation of the reasons for issuance, is reprinted in this document.

DATES: The Authorization is effective as of July 13, 2022.

ADDRESSES: Submit written requests for a single copy of the EUA to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT:

Michael Mair, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4340, Silver Spring, MD 20993–0002, 301–796–8510 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) allows FDA to strengthen public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help ensure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biological, chemical, nuclear, or radiological agents when there are no adequate, approved, and available alternatives (among other criteria).

II. Criteria for EUA Authorization

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological,

or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces, including personnel operating under the authority of title 10 or title 50, U.S. Code, of attack with (A) a biological, chemical, radiological, or nuclear agent or agents; or (B) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces;¹ (3) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or (4) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F–2 of the Public Health Service (PHS) Act (42 U.S.C. 247d–6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the **Federal Register** a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Under section 564(h)(1) of the FD&C Act, revisions to an authorization shall be made available on the internet website of FDA. Section 564 of the FD&C Act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use in an actual or potential emergency when the Secretary of HHS has declared that circumstances exist justifying the

authorization of emergency use. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under sections 505, 510(k), 512, or 515 of the FD&C Act (21 U.S.C. 355, 360(k), 360b, and 360e) or section 351 of the PHS Act (42 U.S.C. 262), or conditionally approved under section 571 of the FD&C Act (21 U.S.C. 360ccc). FDA may issue an EUA only if, after consultation with the HHS Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the applicable circumstances), FDA² concludes: (1) that an agent referred to in a declaration of emergency or threat can cause a serious or life-threatening disease or condition; (2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that: (A) the product may be effective in diagnosing, treating, or preventing (i) such disease or condition; or (ii) a serious or life-threatening disease or condition caused by a product authorized under section 564, approved or cleared under the FD&C Act, or licensed under section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under section 564(b)(1)(D) of the FD&C Act, if applicable; (3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; (4) in the case of a determination described in section 564(b)(1)(B)(ii) of the FD&C Act, that the request for emergency use is made by the Secretary of Defense; and (5) that such other criteria as may be prescribed by regulation are satisfied.

No other criteria for issuance have been prescribed by regulation under section 564(c)(4) of the FD&C Act.

² The Secretary of HHS has delegated the authority to issue an EUA under section 564 of the FD&C Act to the Commissioner of Food and Drugs.

III. The Authorization

The Authorization follows the February 4, 2020, determination by the Secretary of HHS that there is a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves a novel (new) coronavirus. The virus, now named SARS–CoV–2, causes the illness COVID–19. Notice of the Secretary's determination was provided in the **Federal Register** on February 7, 2020 (85 FR 7316). On the basis of such determination, the Secretary of HHS declared on March 27, 2020, 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 FD&C Act, subject to the terms of any authorization issued under that section. Notice of the Secretary's declaration was provided in the **Federal Register** on April 1, 2020 (85 FR 18250). Having concluded that the criteria for issuance of the Authorization under section 564(c) of the FD&C Act are met, FDA has issued the authorization for the emergency use of a biological product during the COVID–19 pandemic. On July 13, 2022, FDA issued an EUA to Novavax, Inc. for the biological product Novavax COVID–19 Vaccine, Adjuvanted, subject to the terms of the Authorization. The initial Authorization, which is included below in its entirety after section IV of this document (not including the authorized versions of the fact sheets and other written materials), provides an explanation of the reasons for issuance, as required by section 564(h)(1) of the FD&C Act. Any subsequent reissuance of the Authorization can be found on FDA's web page at: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

IV. Electronic Access

An electronic version of this document and the full text of the Authorization is available on the internet at: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

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¹ In the case of a determination by the Secretary of Defense, the Secretary of HHS shall determine within 45 calendar days of such determination, whether to make a declaration under section 564(b)(1) of the FD&C Act, and, if appropriate, shall promptly make such a declaration.



July 13, 2022

Novavax, Inc.
Attention: Ms. Kathleen Callahan
21 Firstfield Rd
Gaithersburg, MD 20878

Dear Ms. Callahan:

This letter is in response to a request from Novavax, Inc. that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of the Novavax COVID-19 Vaccine, Adjuvanted for the prevention of Coronavirus Disease 2019 (COVID-19) for individuals 18 years of age and older, as described in the Scope of Authorization (Section II) of this letter, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act or the Act) (21 U.S.C. 360bbb-3).

On February 4, 2020, pursuant to Section 564(b)(1)(C) of 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 COVID-19.¹ 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, subject to terms of any authorization issued under that section.²

The Novavax COVID-19 Vaccine, Adjuvanted is 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 recombinant spike (rS) protein, and saponin-based adjuvant, Matrix-M. The Novavax COVID-19 Vaccine, Adjuvanted is an investigational vaccine not licensed for any indication.

FDA reviewed safety and efficacy data from an ongoing phase 3 trial in which participants 18 years of age and older were randomized 2:1 to receive two doses of Novavax COVID-19 Vaccine, Adjuvanted or placebo, 3 weeks apart. This study includes pre-crossover and post-crossover periods. In the pre-crossover period, 19,735 participants received Novavax COVID-19 Vaccine, Adjuvanted and 9,847 received saline placebo. In the post-crossover period, 6,416

¹ 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.

² 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).

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participants received Novavax COVID-19 Vaccine, Adjuvanted and 15,298 received saline placebo. Of participants who received two doses of Novavax COVID-19 Vaccine, Adjuvanted in the pre-crossover period (n=19,111), 78% had a follow-up duration of at least 2 months (median = 2.5 months) after Dose 2. Of the participants who received two doses of Novavax COVID-19 Vaccine, Adjuvanted in the post-crossover period (n= 6,346), 99% had a follow-up duration of at least 2 months (median = 4.4 months) after the last dose. FDA's review considered the safety and effectiveness data as they relate to the request for emergency use authorization, and did not identify specific safety concerns that would preclude issuance of an EUA. FDA's analysis of the efficacy data from 25,657 participants 18 years of age and older who did not have evidence of SARS-CoV-2 infection through 6 days after the second dose and who had a median follow-up of 2.5 months after Dose 2 during the pre-crossover period shows that the vaccine was 90.4% effective (95% confidence interval (CI): 83.8%, 94.3%) in preventing PCR-confirmed symptomatic mild, moderate, or severe COVID-19 occurring at least 7 days after Dose 2. Based on these data, and the review of manufacturing information regarding product quality and consistency, it is reasonable to believe that the Novavax COVID-19 Vaccine, Adjuvanted 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 the Novavax COVID-19 Vaccine, Adjuvanted outweigh its known and potential risks for the prevention of COVID-19 in individuals 18 years of age and older. Finally, on June 7, 2022, the Vaccines and Related Biological Products Advisory Committee voted in agreement with this conclusion.

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 the Novavax COVID-19 Vaccine, Adjuvanted 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 the Novavax COVID-19 Vaccine, Adjuvanted, 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:

- 1) SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;
- 2) Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Novavax COVID-19 Vaccine, Adjuvanted may be effective in preventing COVID-19, and that, when used under the conditions described in this authorization, the known and potential benefits of the Novavax COVID-19 Vaccine, Adjuvanted when used to prevent COVID-19 outweigh its known and potential risks; and

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- 3) There is no adequate, approved, and available alternative³ to the emergency use of the Novavax COVID-19 Vaccine, Adjuvanted to prevent COVID-19.⁴

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:

- Novavax, Inc. will supply the Novavax COVID-19 Vaccine, Adjuvanted through authorized distributor(s)⁵ to emergency response stakeholders⁶ 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 Novavax COVID-19 Vaccine, Adjuvanted covered by this authorization will be administered by vaccination providers⁷ and used only to prevent COVID-19 in

³ Although Spikevax (COVID-19 Vaccine, mRNA) and Comirnaty (COVID-19 Vaccine, mRNA) are approved to prevent COVID-19 in individuals within the scope of the Novavax COVID-19 Vaccine, Adjuvanted authorization, there are not sufficient quantities of approved vaccine available for distribution to this population in its entirety at the time of reissuance of this EUA. In addition, this vaccine may be an alternative for individuals for whom the approved mRNA COVID-19 vaccines are contraindicated.

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

⁵ “Authorized Distributor(s)” are identified by Novavax, 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 Novavax COVID-19 Vaccine, Adjuvanted.

⁶ 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.

⁷ 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).

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individuals ages 18 and older with a two-dose primary series given 3 weeks apart; and

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

Product Description

The Novavax COVID-19 Vaccine, Adjuvanted is supplied as a suspension in multi-dose vials. The Novavax COVID-19 Vaccine, Adjuvanted does not contain a preservative.

The primary series is two doses (0.5 mL each) given 3 weeks apart.

Each 0.5 mL dose of the Novavax COVID-19 Vaccine, Adjuvanted is formulated to contain 5 mcg of SARS-CoV-2 recombinant spike (rS) protein and 50 mcg Matrix-M adjuvant. The Matrix M adjuvant is composed of Fraction-A (42.5 mcg) and Fraction-C (7.5 mcg) of saponin extracts from the soapbark tree, *Quillaja saponaria* Molina. Each dose of the Novavax COVID-19 Vaccine, Adjuvanted also includes the following ingredients: cholesterol (30.5 mcg), phosphatidylcholine (23 mcg), potassium dihydrogen phosphate (3.85 mcg), potassium chloride (2.25 mcg), disodium hydrogen phosphate dihydrate (14.7 mcg), disodium hydrogen phosphate heptahydrate (2.465 mg), sodium dihydrogen phosphate monohydrate (0.445 mg), sodium chloride (8.856 mg), and polysorbate 80 (0.05 mg) in sterile Water for Injection. The pH is adjusted with sodium hydroxide or hydrochloric acid.

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

The Novavax COVID-19 Vaccine, Adjuvanted vial label and carton labels are clearly marked for "Emergency Use Authorization." The Novavax COVID-19 Vaccine, Adjuvanted 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 Novavax COVID-19 Vaccine, Adjuvanted 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 Novavax COVID-19 Vaccine, Adjuvanted to Prevent Coronavirus Disease 2019 (COVID-19)
- Fact Sheet for Recipients and Caregivers: Emergency Use Authorization (EUA) of the Novavax COVID-19 Vaccine, Adjuvanted to Prevent Coronavirus Disease 2019 (COVID-19)

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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 the Novavax COVID-19 Vaccine, Adjuvanted, 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 the Novavax COVID-19 Vaccine, Adjuvanted 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 the Novavax COVID-19 Vaccine, Adjuvanted (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 the Novavax COVID-19 Vaccine, Adjuvanted 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), the Novavax COVID-19 Vaccine, Adjuvanted 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:

Novavax, Inc. and Authorized Distributor(s)

- A. Novavax, Inc. and authorized distributor(s) will ensure that the authorized Novavax COVID-19 Vaccine, Adjuvanted is distributed, as directed by the U.S. government, including CDC and/or other designee, and the authorized labeling (i.e., Fact Sheets) is made available to vaccination providers, recipients, and caregivers, consistent with the terms of this letter.
- B. Novavax, Inc. and authorized distributor(s) will ensure that appropriate storage and cold chain is maintained until delivered to emergency response stakeholders' receipt sites.
- C. Novavax, 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 the authorized Novavax COVID-19 Vaccine, Adjuvanted. Novavax, 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. Novavax, 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. Novavax, Inc. may request changes to this authorization, including to the authorized Fact Sheets for the Novavax COVID-19 Vaccine, Adjuvanted. Any request for changes to this EUA must be submitted to the Office of Vaccines Research and Review (OVR) / Center for Biologics Evaluation and Research (CBER). Such changes require appropriate authorization prior to implementation.⁸

F. Novavax, 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 Novavax, 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 Novavax, Inc.

G. Novavax, Inc. must submit to Investigational New Drug application (IND) number 22430 periodic safety reports at monthly intervals 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

⁸ 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 OVR. For changes to the authorization, including the authorized labeling, of the type listed in (3), (6), or (7), review and concurrence is also 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).

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- 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 the Agency.
- I. All manufacturing facilities will comply with Current Good Manufacturing Practice requirements.
- J. Novavax, 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. Novavax, Inc. will submit to the EUA file quarterly manufacturing reports 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. The first report is due October 13, 2022.
- L. Novavax, Inc. and authorized distributor(s) will maintain records regarding release of Novavax COVID-19 Vaccine, Adjuvanted for distribution (i.e., lot numbers, quantity, release date).
- M. Novavax, Inc. and authorized distributor(s) will make available to FDA upon request any records maintained in connection with this EUA.
- N. Novavax, Inc. will conduct post-authorization observational studies to evaluate the association between Novavax COVID-19 Vaccine, Adjuvanted 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 Novavax COVID-19 Vaccine, Adjuvanted under this EUA in the general U.S. population (18 years of age and older), 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. Novavax, Inc. will provide protocols and status update reports to the IND 22430 with agreed-upon study designs and milestone dates.

Emergency Response Stakeholders

- O. Emergency response stakeholders will identify vaccination sites to receive authorized Novavax COVID-19 Vaccine, Adjuvanted and ensure its distribution and

administration, consistent with the terms of this letter and CDC's COVID-19 Vaccination Program.

- P. 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).
- Q. Emergency response stakeholders receiving authorized Novavax COVID-19 Vaccine, Adjuvanted will ensure that appropriate storage and cold chain is maintained.

Vaccination Providers

- R. 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.
- S. 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.
- T. Vaccination providers administering the Novavax COVID-19 Vaccine, Adjuvanted must report the following information associated with the administration of the Novavax COVID-19 Vaccine, Adjuvanted 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 "Novavax COVID-19 Vaccine, Adjuvanted 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 Novavax, Inc. by contacting 1-844-668-2829 or by providing a copy of the VAERS form to Novavax, Inc.; Fax: 1-888-988-8809.
- U. 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.

- V. 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.
- W. 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

- X. All descriptive printed matter, advertising, and promotional material, relating to the use of the Novavax COVID-19 Vaccine, Adjuvanted 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.
- Y. All descriptive printed matter, advertising, and promotional material relating to the use of the Novavax COVID-19 Vaccine, Adjuvanted 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

- Z. If the Novavax COVID-19 Vaccine, Adjuvanted is exported from the United States, conditions C, D, and O through Y 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.

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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,

/s/

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

Enclosures

Dated: August 22, 2022.

Lauren K. Roth,*Associate Commissioner for Policy.*

[FR Doc. 2022–18527 Filed 8–26–22; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****[Docket No. FDA–2022–D–1527]****M12 Drug Interaction Studies; International Council for Harmonisation; Draft Guidance for Industry; Availability****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “M12 Drug Interaction Studies.” The draft guidance was prepared under the auspices of the International Council for Harmonisation (ICH), formerly the International Conference on Harmonisation. The draft guidance provides general recommendations on how to evaluate the pharmacokinetic drug interaction potential mediated via enzyme and transporter for investigational drugs. The draft guidance harmonizes the regional requirements on in vitro and clinical evaluation of drug-drug interactions for a more consistent approach in design, conduct, and interpretation of enzyme and transporter-mediated interaction during the development of an

investigational drug. The draft guidance is intended to decrease the risk of adverse events, sometimes leading to hospital admissions or reduced treatment efficacy.

DATES: Submit either electronic or written comments on the draft guidance by September 28, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the

manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2022–D–1527 for “M12 Drug Interaction Studies.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- *Confidential Submissions—*To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the