U.S. FOOD & DRUG ADMINISTRATION

March 14, 2023

Karl Guenther
(b) (6)

Sent via email to: (b) (6)

RE: Citizen Petition (Docket Number: FDA-2022-P-3121)

Dear Petitioner,

This letter responds to the following citizen petitions that you (Petitioner) submitted to the Food and Drug Administration (FDA, the Agency, we) relating to the authorization of certain COVID-19 vaccines:

- The citizen petition (the Petition) dated December 6, 2022.
- The amended citizen petition (the Amended Petition) dated January 26, 2023. (Collectively, the Petitions)

In the Petition, Petitioner lists the following as "actions requested":

1. Disallow all Vaccine Mandates for All Vaccines; and
2. Revoke Authorization for All Covid 19 Vaccines; and
3. Disallow Authorization for Any Newly Requested Covid 19 Authorizations.[1]

In the Amended Petition, the Petitioner reiterated the requests and information in the Petition and added additional information for the Agency to consider.[2]

This letter responds to the Petitions in full. We have carefully reviewed the Petitions and other information available to the Agency. Based on our review of these materials, and for the reasons described below, we conclude that the Petitions do not contain facts demonstrating any reasonable grounds for the requested actions. In accordance with Title 21 CFR (Code of Federal Regulations) 10.30(e)(3), and for the reasons stated below, FDA is denying the Petitions.

Here is an outline of FDA's response:

[1] Petition at 1. We note that the Amended Petition lists the same "actions requested" as the Petition. Amended Petition at 1.
[2] Because the Amended Petition incorporates the arguments and information in the Petition, any responses referencing the "Petition" also apply to the Amended Petition.

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## I. BACKGROUND

There is currently a pandemic of respiratory disease, COVID-19, caused by a novel coronavirus, SARS-CoV-2. The COVID-19 pandemic presents an extraordinary challenge to global health. On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19.[3] On February 4, 2020, pursuant to section

[3] Secretary of HHS Alex M. Azar, Determination that a Public Health Emergency Exists (Originally issued on Jan. 31, 2020, and subsequently renewed), https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx.

564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Secretary of 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 (U.S.) citizens living abroad, and that involves the virus that causes COVID-19.[4] On the basis of such determination, on March 27, 2020, the Secretary then declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic ("COVID-19 EUA Declaration"), pursuant to section 564(b)(1) of the FD&C Act.[5] In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.[6]

Commercial vaccine manufacturers and other entities have developed and are developing COVID-19 vaccines, and clinical studies of these vaccines are underway and/or have been publicly reported. Between December 11, 2020 and July 13, 2022, FDA issued EUAs for four vaccines to prevent COVID-19, including vaccines sponsored by Pfizer Inc. (Pfizer)[7], ModernaTX, Inc. (Moderna)[8], Novavax Inc. (Novavax)[9], and Janssen BioTech, Inc. (Janssen)[10]. The EUAs have been amended since initial issuance.

On August 23, 2021, the Agency approved the Biologics License Application (BLA) for Comirnaty (COVID-19 Vaccine, mRNA), and the approval was granted to BioNTech Manufacturing GmbH.[11] Comirnaty is indicated for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 12 years of age and older. On January 31, 2022, the Agency approved the BLA for Spikevax (COVID-19 Vaccine, mRNA), and the approval was granted to Moderna. Spikevax is indicated for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older.

[4] HHS, Determination of Public Health Emergency, 85 FR 7316, February 7, 2020, https://www.federalregister.gov/documents/2020/02/07/2020-02496/determination-of-public-health-emergency.
[5] HHS, Emergency Use Authorization Declaration, 85 FR 18250, April 1, 2020, https://www.federalregister.gov/documents/2020/04/01/2020-06905/emergency-use-authorization-declaration.
[6] Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak, issued March 13, 2020, https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/.
[7] Hereinafter "Pfizer-BioNTech COVID-19 Vaccine".
[8] Hereinafter "Moderna COVID-19 Vaccine".
[9] Hereinafter "Novavax COVID-19 Vaccine, Adjuvanted".
[10] Hereinafter "Janssen COVID-19 Vaccine".
[11] BioNTech Manufacturing GmbH is the biologics license holder for this vaccine, which is manufactured by Pfizer for BioNTech Manufacturing GmbH.

## II. VACCINES THAT ARE FDA-LICENSED OR RECEIVE AN EMERGENCY USE AUTHORIZATION MEET RELEVANT STATUTORY REQUIREMENTS

### A. Investigational New Drugs

FDA's investigational new drug process applies to the development of new drugs and biological products, including vaccines.[12] Before a vaccine is licensed (approved) by FDA for use by the public, FDA requires that it undergo a rigorous and extensive development program to determine the vaccine's safety and effectiveness. This development program encompasses preclinical research (laboratory research, animal studies[13]) and clinical studies. At the preclinical stage, the sponsor focuses on collecting the data and information necessary to establish that the product will not expose humans to unreasonable risks when used in limited, early-stage clinical studies. Clinical studies, in humans, are conducted under well-defined conditions and with careful safety monitoring through all the phases of the investigational new drug process. FDA's regulations governing the conduct of clinical investigations are set out at 21 CFR Part 312.

Before conducting a clinical investigation in the U.S. in which a new drug or biological product is administered to humans, a sponsor must submit an investigational new drug application (IND) to FDA.[14] The IND describes the proposed clinical study in detail and, among other things, helps protect the safety and rights of human subjects.[15] In addition to other information, an IND must contain information on clinical protocols and clinical investigators.[16] Detailed protocols for proposed clinical studies permit FDA to assess whether the initial-phase trials will expose subjects to unnecessary risks. Information on the qualifications of clinical investigators (professionals, generally physicians, who oversee the administration of the investigational drug) permits FDA to assess whether they are qualified to fulfill their clinical trial duties. The IND includes commitments to obtain informed consent from the research subjects, to obtain review of the study by an institutional review board (IRB),[17] and to adhere to the IND regulations.

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[12] See 21 CFR 312.2(a) (explaining that the regulations in 21 CFR Part 312 apply to clinical investigations of both drugs and biologics).

[13] We support the principles of the "3Rs," to reduce, refine, and replace animal use in testing when feasible. We encourage sponsors to consult with us if they wish to use a non-animal testing method they believe is suitable, adequate, validated, and feasible. We will consider if such an alternative method could be assessed for equivalency to an animal test method.

[14] See 21 CFR 312.20(a).

[15] For additional information regarding the IND review process and general responsibilities of sponsor-investigators related to clinical investigations see Investigational New Drug Applications Prepared and Submitted by Sponsor-Investigators; Draft Guidance for Industry, May 2015, https://www.fda.gov/media/92604/download. This draft guidance, when finalized, will represent the current thinking of the Agency on this topic.

[16] See, e.g., 21 CFR 312.23(a)(6).

[17] The IRB is a panel of scientists and non-scientists in hospitals and research institutions that oversees clinical research. IRBs approve clinical study protocols, which describe the type of people who may participate in the clinical study; the schedule of tests and procedures; the medications and dosages to be studied; the length of the study; the study's objectives; and other details. IRBs make sure that the study is acceptable, that participants have given consent and are fully informed of the risks, and that researchers take appropriate steps to protect patients from harm. See The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective web page, last updated November 2017, https://www.fda.gov/drugs/drug-information-consumers/fdas-drug-review-process-ensuring-drugs-are-safe-and-effective.

Once the IND is submitted, the sponsor must wait 30 calendar days before initiating any clinical trials, unless FDA informs the sponsor that the trial may begin earlier. During this time, FDA reviews the IND. FDA's primary objectives in reviewing an IND are, in all phases of the investigation, to assure the safety and rights of subjects, and, in Phase 2 and Phase 3, to help assure that the quality of the scientific evaluation of drugs is adequate to permit an evaluation of the drug's effectiveness and safety.[18]

FDA's regulations provide that, once an IND is in effect, the sponsor may conduct a clinical investigation of the product, with the investigation generally being divided into three phases. With respect to vaccines, the initial human studies, referred to as Phase 1 studies, are generally safety and immunogenicity studies performed in a small number of closely monitored subjects. Phase 2 studies may include up to several hundred individuals and are designed to provide information regarding the incidence of common short-term side effects such as redness and swelling at the injection site or fever and to further describe the immune response to the investigational vaccine. If an investigational new vaccine progresses past Phase 1 and Phase 2 studies, it may progress to Phase 3 studies. For Phase 3 studies, the sample size is often determined by the number of subjects required to establish the effectiveness of the new vaccine, which may be in the thousands or tens of thousands of subjects. Phase 3 studies provide the critical documentation of effectiveness and important additional safety data required for licensing.

At any stage of development, if data raise significant concerns about either safety or effectiveness, FDA may request additional information or studies; FDA may also halt ongoing clinical studies. The FD&C Act provides a specific mechanism, called a "clinical hold," for prohibiting sponsors of clinical investigations from conducting the investigation (section 505(i)(3) of the FD&C Act; 21 U.S.C. § 355(i)(3)), and FDA's IND regulations in 21 CFR 312.42 identify the circumstances that may justify a clinical hold. Generally, a clinical hold is an order issued by FDA to the sponsor of an IND to delay a proposed clinical investigation or to suspend an ongoing investigation.[19]

### B. Licensed Vaccines Are Safe, Pure, and Potent

FDA has a stringent regulatory process for licensing vaccines.[20, 21] The Public Health Service Act (PHS Act) authorizes FDA to license biological products, including vaccines, if they have been demonstrated to be "safe, pure, and potent."[22] Prior to approval by FDA, vaccines are extensively tested in non-clinical studies and in humans. FDA's regulations describe some of the

[18] 21 CFR 312.22(a).
[19] 21 CFR 312.42(a).
[20] CDC, Ensuring the Safety of Vaccines in the United States, February 2013, https://www.cdc.gov/vaccines/hcp/patient-ed/conversations/downloads/vacsafe-ensuring-bw-office.pdf.
[21] Vaccine Safety Questions and Answers, last updated March 2018, https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/vaccine-safety-questions-and-answers.
[22] Section 351(a)(2)(C)(i)(I) of the PHS Act.

extensive data and information that each sponsor of a BLA for a vaccine must submit to FDA in order to demonstrate the product's safety, purity, and potency before FDA will consider licensing the vaccine. FDA requires that the sponsor's application include, among other things, data derived from nonclinical and clinical studies showing the product's safety, purity, and potency; a full description of manufacturing methods for the product; data establishing the product's stability through the dating period; and representative sample(s) of the product and summaries of results of tests performed on the lot(s) represented by the sample.[23]

As is evident from the language of the PHS Act and FDA's regulations, the licensure process for a vaccine requires the sponsor to establish, through carefully controlled laboratory and clinical studies, as well as through other data, that the product is safe and effective for its proposed uses. FDA's multidisciplinary review teams then rigorously evaluate the sponsor's laboratory and clinical data, as well as other information, to help assess whether the safety, purity, and potency of a vaccine have been demonstrated.[24] Only when FDA's standards are met is a vaccine licensed.

FDA regulations explicitly state that "[a]pproval of a biologics license application or issuance of a biologics license shall constitute a determination that the establishment(s) and the product meet applicable requirements to ensure the continued safety, purity, and potency of such products."[25] Therefore, the manufacturers of vaccines that have been licensed in the U.S. have necessarily demonstrated the safety, purity, and potency of the vaccines within the meaning of the applicable statutory and regulatory provisions before the vaccines were licensed and allowed to be marketed.

### C. An Emergency Use Authorization for a COVID-19 Preventative Vaccine Is Issued Only If the Relevant Statutory Standards Are Met

Congress established the EUA pathway to ensure that, during public health emergencies, potentially lifesaving medical products could be made available before being approved. The EUA process allows the Secretary of HHS, in appropriate circumstances, to declare that EUAs are justified for products to respond to certain types of threats. When such a declaration is made, FDA may issue an EUA, which is different from the regulatory process for vaccine licensure.

Section 564 of the FD&C Act authorizes FDA to, under certain circumstances, issue an EUA to allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by chemical, biological, radiological, or nuclear (CBRN) threat agents when there are no adequate, approved, and available alternatives.

On February 4, 2020, pursuant to section 564(b)(1)(C) of the FD&C Act, the Secretary of HHS determined 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 the

[23] 21 CFR 601.2(a).
[24] FDA, Vaccines, last updated February 2023, https://www.fda.gov/vaccines-blood-biologics/vaccines.
[25] 21 CFR 601.2(d).

virus that causes COVID-19.[26] On the basis of such determination, on March 27, 2020, the Secretary then declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to section 564(b)(1) of the FD&C Act.[27]

Based on this declaration and determination, under section 564(c) of the FD&C Act, FDA may issue an EUA during the COVID-19 pandemic after FDA concludes that the following statutory requirements are met:

- The agent referred to in the COVID-19 EUA Declaration by the Secretary (SARS-CoV-2) can cause a serious or life-threatening disease or condition.

- Based on the totality of scientific evidence available, including data from adequate and well-controlled trials, if available, it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing such serious or life-threatening disease or condition that can be caused by SARS-CoV-2.

- The known and potential benefits of the product, when used to diagnose, prevent, or treat the identified serious or life-threatening disease or condition, outweigh the known and potential risks of the product.

- There is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating the disease or condition.

Although EUAs are governed under a different statutory framework than BLAs, FDA has made clear that issuance of an EUA for a COVID-19 vaccine would require that the vaccine demonstrated clear and compelling safety and efficacy in a large, well-designed Phase 3 clinical trial. In the guidance document *Emergency Use Authorization for Vaccines to Prevent COVID-19* (EUA Vaccine Guidance), FDA has provided recommendations that describe key information that would support issuance of an EUA for a vaccine to prevent COVID-19.[28] In the EUA Vaccine Guidance, FDA explained that, in the case of such investigational vaccines, any assessment regarding an EUA will be made on a case-by-case basis considering the target population, the characteristics of the product, the preclinical and human clinical study data on the product, and the totality of the available scientific evidence relevant to the product.[29] FDA has also stated, in this guidance, that for a COVID-19 vaccine for which there is adequate manufacturing information to ensure its quality and consistency, issuance of an EUA would require a determination by FDA that the vaccine's benefits outweigh its risks based on data from at least one well-designed Phase 3 clinical trial that demonstrates the vaccine's safety and efficacy in a clear and compelling manner.[30]

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[26] HHS, Determination of Public Health Emergency, 85 FR 7316, February 7, 2020, https://www.federalregister.gov/documents/2020/02/07/2020-02496/determination-of-public-health-emergency.
[27] COVID-19 EUA Declaration.
[28] Emergency Use Authorization for Vaccines to Prevent COVID-19; Guidance for Industry, March 2022, (EUA Vaccine Guidance), https://www.fda.gov/media/142749/download.
[29] *Id.* at 4.
[30] *Id.*

A Phase 3 trial of a vaccine is generally a clinical trial in which a large number of people are assigned to receive the investigational vaccine or a control. In general, in Phase 3 trials that are designed to show whether a vaccine is effective, neither people receiving the vaccine nor those assessing the outcome know who received the vaccine or the comparator.

In a Phase 3 study of a COVID-19 vaccine, the efficacy of the investigational vaccine to prevent disease will be assessed by comparing the number of cases of disease in each study group. For Phase 3 placebo- controlled efficacy trials, FDA has recommended to manufacturers in guidance that the vaccine should be at least 50% more effective than the comparator, and that the outcome be reliable enough so that it is not likely to have happened by chance.[31] During the entire study, subjects will be monitored for safety events. If the evidence from the clinical trial meets the pre-specified criteria for success for efficacy and the safety profile is acceptable, the results from the trial can potentially be submitted to FDA in support of an EUA request.

During the current public health emergency, manufacturers may, with the requisite data and taking into consideration input from FDA, choose to submit a request for an EUA. It is FDA's expectation that, following submission of an EUA request and issuance of an EUA, a sponsor would continue to evaluate the vaccine and would also work towards submission of a BLA as soon as possible.[32]

### D. FDA Periodically Reviews Authorizations and May Revise or Revoke an Emergency Use Authorization if the Issuance Criteria Are No Longer Met

An EUA will remain in effect until the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products is terminated under section 564(b)(2) of the FD&C Act or the EUA is revoked under section 564(g) of the FD&C Act. Section 564(g) provides that "[t]he Secretary shall periodically review the circumstances and the appropriateness of an authorization" under section 564. In addition, section 564(g)(2) states the Secretary "may revise or revoke an authorization" if:

- the circumstances described under [section 564(b)(1) of the FD&C Act] no longer exist;
- the criteria under [section 564(c) of the FD&C Act] for issuance of such authorization are no longer met; or
- other circumstances make such revision or revocation appropriate to protect the public health or safety.

[31] Development and Licensure of Vaccines to Prevent COVID-19; Guidance for Industry, June 2020, (Vaccine Development and Licensure Guidance), https://www.fda.gov/media/139638/download.
[32] *Id.*

Consistent with these provisions and section 564(g)(1) of the FD&C Act, FDA periodically reviews the circumstances and appropriateness of an EUA and revises or revokes an EUA if the criteria in section 564(g)(2) are met and if certain circumstances exist.[33]

## III. DISCUSSION

### A. Petitioner's Request that FDA Disallow All Vaccine Mandates for All Vaccines

Petitioner requests that FDA "Disallow all Vaccine Mandates for All Vaccines."[34] Petitioner asserts that "[a]ny vaccines authorized at the federal level in the U.S. should only be authorized with a stipulation that none of their usage can be mandated at the federal or lower levels of government or by any other individual or company."[35] Petitioner also makes several statements concerning vaccine usage generally.[36, 37]

With regard to vaccine mandates and whether it is lawful for third parties to require vaccination with FDA-authorized vaccines, we refer you to the Memorandum Opinion for the Deputy Counsel to the President available on the United States Department of Justice website.[38] We note that FDA's EUAs and BLA approvals do not address whether third parties may require individuals to receive vaccines, and there is no legal requirement that the EUAs or BLA approvals address this topic. You have not explained why a condition "that none of their usage can be mandated at the federal or levels of government or by any other individual or company" is required by FDA's EUA authority. Concerns about potential third party vaccine requirements are better directed to those parties.

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[33] Emergency Use Authorization of Medical Products and Related Authorities; Guidance for Industry and Other Stakeholders, January 2017, (EUA Guidance), at 29, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities.

[34] Petition at 1.

[35] *Id.* at 2.

[36] We note that Petitioner asserts that "[g]iven the use of antivirals, antibiotics, antibody treatments, and other treatments, the mandating of vaccine usage is out of date with modern science and personal preferences of most people of the United States." Petition at 2. Additionally, Petitioner further states "that we need to generally reduce the use of vaccines to allow the human immune system to develop and adapt to the requirements of individuals" (Petition at 7) and that "[t]he world would be much better off if it had stopped working vaccine development decades ago and gone into antiviral research and development along with medical development like with antibody treatments and other forward looking medical development" (Petition at 6). Petitioner provides no data to support any of these assertions. We also note that the Petition references a publication (Malhotra, A., Curing the pandemic of misinformation on COVID-19 mRNA vaccines through real evidence-based medicine - Part 1, J. Insul. Resist., 2022;5(1), a71. https://doi.org/10.4102/jir.v5i1.71) that Petitioner states "has come to the same conclusion on Covid 19 MRNA vaccines via a different mathematical and scientific analysis" as the Petition. Petition at 2. The referenced publication does not provide any data or information that would change FDA's evaluation of the mRNA COVID-19 vaccines.

[37] Petitioner also references a separate Citizen Petition, Docket No. FDA-2021-P-1320, submitted by the Petitioner concerning pertussis vaccines and makes several assertions relevant to this separate Citizen Petition. This response letter addresses only the requested actions outlined in the Citizen Petition dated Dec. 6, 2022 and the Amended Petition dated Jan. 26, 2023, submitted by Petitioner and filed at Docket No. FDA-2022-P-3121.

[38] *See* https://www.justice.gov/sites/default/files/opinions/attachments/2021/07/26/2021-07-06-mand-vax.pdf.

For these reasons, FDA denies Petitioner's request for FDA to disallow all vaccine mandates.

### B. Petitioner's Request that FDA Revoke Authorizations for all COVID-19 Vaccines

Petitioner requests that FDA "Revoke Authorization for all COVID 19 Vaccines Which Includes these Links that Link to the FDA pages on those Vaccines Below, plus any other Covid 19 Vaccines not listed."[39] Petitioner then provides links to FDA website information on the COVID-19 vaccines sponsored by Pfizer, Moderna, Janssen, and Novavax. The links provided by Petitioner also include information on Comirnaty and Spikevax, which are the only licensed vaccines indicated to prevent COVID-19 in any population.

We interpret this as a request for FDA to revoke the authorizations for emergency use of the vaccines sponsored by the aforementioned sponsors[40] as well as a request for FDA to revoke the biologics licenses for Comirnaty and Spikevax.

Below we address this request and the information submitted by Petitioner in support of this requested action.

#### i. EUAs and the BLAs for COVID-19 Vaccines

As explained above in Section I of this letter, FDA has issued EUAs for four monovalent[41] vaccines and two bivalent[42] vaccines to prevent COVID-19, including vaccines sponsored by Pfizer, Moderna, Janssen, and Novavax (Authorized COVID-19 Vaccines). The EUAs have been amended since initial issuance. FDA has also approved BLAs for Comirnaty and Spikevax.

##### a. EUA for the Pfizer-BioNTech COVID-19 Vaccine and the BLA for Comirnaty

On December 11, 2020, FDA issued an EUA for emergency use of Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 in individuals 16 years of age and older. The EUA was

[39] Petition at 1.
[40] Petitioner also states "plus any Other Covid 19 Vaccines not listed." Petition at 1. There are currently no other COVID-19 vaccines authorized for emergency use except those sponsored by Pfizer, Moderna, Janssen, and Novavax.
[41] For the purposes of this letter, monovalent refers to any FDA authorized or approved COVID-19 vaccine that contains or encodes the spike protein of only the Original SARS-CoV-2.
[42] For the purposes of this letter, unless otherwise specified, bivalent refers to any FDA authorized COVID-19 vaccine that encodes the spike protein of the Original SARS-CoV-2 and the Omicron BA.4/BA.5 SARS-CoV-2.

subsequently amended.[43] Currently, the Pfizer-BioNTech COVID-19 Vaccine[44] is authorized for emergency use as:

- The first two doses of the three-dose primary series for individuals 6 months through 4 years of age.
- A two-dose primary series for individuals 5 years of age and older.
- A third primary series dose for individuals 5 years of age and older who have been determined to have certain kinds of immunocompromise.

On August 31, 2022, the EUA was amended to authorize a bivalent vaccine sponsored by Pfizer[45] as a single booster dose for the prevention of COVID-19 in individuals 12 years of age and older. The EUA has since been amended to authorize use of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent in individuals 6 months of age and older. Currently, Pfizer-BioNTech COVID-19 Vaccine, Bivalent is authorized for emergency use to prevent COVID-19 as:

- The third dose of the three-dose primary series following two doses of the monovalent Pfizer-BioNTech COVID-19 Vaccine in children 6 months through 4 years of age.
- A single booster dose at least two months after completion of either primary vaccination with any authorized or approved COVID-19 vaccine or receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine in individuals 5 years of age and older.

The Agency issued the EUA for the Pfizer-BioNTech COVID-19 Vaccine, and has subsequently amended this EUA, after a thorough evaluation of scientific data regarding the safety and effectiveness and after reaching a determination that the vaccine meets the statutory requirements under section 564 of the FD&C Act. This letter incorporates by reference the EUA Review Memoranda,[46] which discuss these determinations, and the data upon which they were based, in detail.[47]

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[43] For a description of all revisions to the EUA, see Pfizer-BioNTech COVID-19 Vaccine Letter of Authorization, December 8, 2022. This Letter of Authorization is posted on www fda.gov.

[44] Comirnaty is the proprietary name for the product licensed under the BLA. The Pfizer-BioNTech COVID-19 Vaccine has been available since December 11, 2020, pursuant to EUA. The two approved formulations of Comirnaty are the same formulations, respectively, as the two FDA-authorized monovalent formulations of Pfizer-BioNTech COVID-19 Vaccine for individuals ≥12 years, and vials of the BLA-compliant vaccine may bear the name "Pfizer-BioNTech COVID-19 Vaccine." Because of these features, and because Comirnaty is commonly referred to as the "Pfizer vaccine" or the "Pfizer-BioNTech COVID-19 Vaccine," certain references in this section to "Pfizer-BioNTech COVID-19 Vaccine" may also be applicable to uses of Comirnaty that are authorized under EUA.

[45] Hereinafter "Pfizer-BioNTech COVID-19 Vaccine, Bivalent".

[46] FDA, Pfizer-BioNTech COVID-19 Vaccine EUA Decision Memoranda and Addenda to Decision Memoranda, dated December 11, 2020; May 10, 2021; August 12, 2021; September 22, 2021; October 20, 2021; October 29, 2021; November 18, 2021; November 19, 2021; December 8, 2021; December 30, 2021; January 6, 2022; March 28, 2022; May 17, 2022; June 16, 2022; August 31, 2022; October 11, 2022; December 8, 2022 (referred to collectively in this response as "FDA's Pfizer-BioNTech COVID-19 Vaccine EUA Decision Memoranda and Addenda"), available at https://www fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine.

[47] *See also* FDA's Summary Basis for Regulatory Action (SBRA) for Comirnaty, available at https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine#comirnaty.

On August 23, 2021, FDA approved the BLA for Comirnaty, and a supplement to the BLA was approved by FDA on July 8, 2022.[48] Comirnaty had been known as the Pfizer-BioNTech COVID-19 Vaccine, and the approved vaccine is marketed as Comirnaty, for the prevention of COVID-19 in individuals 12 years of age and older. Comirnaty is a monovalent COVID-19 vaccine that is approved for use as a two-dose primary series for the prevention of COVID-19 in individuals 12 years of age and older. It is also authorized for emergency use to provide a third primary series dose to individuals 12 years of age and older with certain kinds of immunocompromise.

The Agency approved Comirnaty after a thorough evaluation of scientific data regarding the safety and effectiveness and after reaching a determination that the vaccine is safe, pure, and potent. This letter incorporates by reference the regulatory information and the clinical review memos of Comirnaty, which discuss this determination, and the data upon which it was based, in detail.[49]

### b. EUA for the Moderna COVID-19 Vaccine and the BLA for Spikevax

On December 18, 2020, FDA issued an EUA for emergency use of the Moderna COVID-19 Vaccine for the prevention of COVID-19 for individuals 18 years of age and older. The EUA was subsequently amended.[50] Currently, the Moderna COVID-19 Vaccine[51] is authorized for emergency use as a:

- Two-dose primary series for individuals 6 months of age and older,
- Third primary series dose for individuals 6 months of age and older who have been determined to have certain kinds of immunocompromise.

On August 31, 2022, the EUA was amended to authorize a bivalent vaccine sponsored by Moderna[52] as a single booster dose for the prevention of COVID-19 in individuals 18 years of age and older. The EUA has since been subsequently amended to authorize use of the Moderna COVID-19 Vaccine, Bivalent in individuals 6 months of age and older. Currently, the Moderna COVID-19 Vaccine, Bivalent is authorized for use as a single booster dose to prevent COVID-19, administered at least 2 months after:

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[48] FDA approved the BLA for Comirnaty for the prevention of COVID-19 in individuals 16 years of age and older on August 23, 2021. A supplement to the BLA was approved on July 8, 2022 for the prevention of COVID-19 in individuals 12 through 15 years of age.

[49] Available at https://www.fda.gov/vaccines-blood-biologics/Comirnaty.

[50] For a description of all revisions to the EUA, see Moderna COVID-19 Vaccine Letter of Authorization, December 8, 2022. This Letter of Authorization is posted on www.fda.gov.

[51] Spikevax is the proprietary name for the product licensed under the BLA. The Moderna COVID-19 Vaccine has been available since December 18, 2020, pursuant to EUA. The approved formulation of Spikevax and the FDA-authorized Moderna COVID-19 Vaccine for providing the primary series in individuals ≥12 years are the same formulation. Because of these features, and because Spikevax may be commonly referred to as the "Moderna vaccine" or the "Moderna COVID-19 Vaccine," certain references in this section to "the Moderna COVID-19 Vaccine" may also be applicable to uses of Spikevax that are authorized under EUA.

[52] Hereinafter "Moderna COVID-19 Vaccine, Bivalent".

- Completion of primary vaccination with the monovalent Moderna COVID-19 Vaccine in children 6 months through 5 years of age, or
- Completion of primary vaccination with any authorized or approved COVID-19 vaccine in individuals 6 years of age and older, or
- Receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine in individuals 6 years of age and older.

The Agency issued the EUA for the Moderna COVID-19 Vaccine, and has subsequently amended this EUA, after a thorough evaluation of scientific data regarding the safety and effectiveness and after reaching a determination that the vaccine meets the statutory requirements under section 564 of the FD&C Act. This letter incorporates by reference the EUA Review Memoranda, which discuss these determinations, and the data upon which they were based, in detail.[53]

On January 31, 2022, the FDA approved the BLA for Spikevax. Spikevax had been known as the Moderna COVID-19 Vaccine, and is now marketed as Spikevax, for the prevention of COVID-19 in individuals 18 years of age and older. Spikevax is a monovalent COVID-19 vaccine that is approved for use as a two-dose primary series for the prevention of COVID-19 in individuals 18 years of age and older. It is also authorized for emergency use to provide:

- A two-dose primary series to individuals 12 years through 17 years of age.
- A third primary series dose to individuals 12 years of age and older with certain kinds of immunocompromise.

The Agency approved the BLA for Spikevax after a thorough evaluation of scientific data regarding the safety and effectiveness and after reaching a determination that the vaccine is safe, pure, and potent. This letter incorporates by reference the summary basis for regulatory action and the clinical review memo of Spikevax, which discuss this determination, and the data upon which it was based, in detail.[54]

### c. EUA for the Janssen COVID-19 Vaccine

On February 27, 2021, FDA issued an EUA for emergency use of the Janssen COVID-19 Vaccine for the prevention of COVID-19 for individuals 18 years of age and older. The EUA has been subsequently amended.[55]

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[53] FDA, Moderna COVID-19 Vaccine EUA Decision Memoranda and Addenda to Decision Memoranda, dated December 18, 2020; August 12, 2021; October 20, 2021; November 18, 2021; November 19, 2021; December 30, 2021; January 6, 2022; March 28, 2022; June 16, 2022; August 31, 2022; September 20, 2022; September 26, 2022; September 28, 2022; October 6, 2022; October 11, 2022; October 14, 2022; October 20, 2022; October 28, 2022; November 4, 2022; November 19, 2022; November 28, 2022; December 8, 2022 (referred to collectively in this response as "FDA's Moderna COVID-19 Vaccine EUA Decision Memoranda and Addenda"), available at https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/spikevax-and-moderna-covid-19-vaccine.

[54] *See* FDA's Summary Basis for Regulatory Action (SBRA) for Spikevax, available at https://www.fda.gov/vaccines-blood-biologics/spikevax.

[55] For a description of all revisions to the EUA, see Janssen COVID-19 Vaccine Letter of Authorization, March 13, 2023. This Letter of Authorization is posted on www fda.gov.

On May 5, 2022, FDA limited the authorized use of the Janssen COVID-19 Vaccine to individuals 18 years of age and older for whom other authorized or approved COVID-19 vaccines are not accessible or clinically appropriate, and to individuals 18 years of age and older who elect to receive the Janssen COVID-19 Vaccine because they would otherwise not receive a COVID-19 vaccine. For these individuals, the Janssen COVID-19 Vaccine is currently authorized for emergency use as a:

- Single primary vaccination dose.
- First booster dose at least 2 months after completion of primary vaccination with an authorized or approved COVID-19 vaccine.

The Agency issued the EUA for the Janssen COVID-19 Vaccine, and has subsequently amended it, after a thorough evaluation of scientific data regarding the safety and effectiveness and after reaching a determination that the vaccine meets the statutory requirements under section 564 of the FD&C Act. This letter incorporates by reference the EUA Review Memoranda, which discuss this determination, and the data upon which it was based, in detail.[56]

### d. EUA for the Novavax COVID-19 Vaccine, Adjuvanted

On July 13, 2022, FDA issued an EUA for emergency use of the Novavax COVID-19 Vaccine, Adjuvanted[57] sponsored by Novavax to prevent COVID-19 in individuals 18 years of age and older. The EUA was subsequently amended.[58] Currently, the Novavax COVID-19 Vaccine, Adjuvanted is authorized for emergency use as a:

- Two-dose primary series for individuals 12 years of age and older.
- First booster dose to the following individuals at least 6 months after completion of primary vaccination with an authorized or approved COVID-19 vaccine:
    - Individuals 18 years of age and older for whom an FDA-authorized mRNA bivalent COVID-19 booster vaccine is not accessible or clinically appropriate.
    - Individuals 18 years of age and older who elect to receive the Novavax COVID-19 Vaccine, Adjuvanted because they would otherwise not receive a booster dose of a COVID-19 vaccine.

[56] FDA, Janssen COVID-19 Vaccine EUA Decision Memoranda and Addenda to Decision Memoranda, dated February 27, 2021; June 11, 2021; June 15, 2021; July 1, 2021; July 13, 2021; September 8, 2021; September 14, 2021; September 28, 2021; October 20, 2021; November 5, 2021; November 18, 2021; December 22, 2021; December 30, 2021; January 6, 2022; January 7, 2022; May 5, 2022; March 13, 2023 (referred to collectively in this response as "FDA's Janssen COVID-19 Vaccine EUA Decision Memoranda and Addenda"), available at https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine.

[57] The Novavax COVID-19 Vaccine contains the SARS-CoV-2 spike protein and Matrix-M adjuvant. Adjuvants are incorporated into some vaccines to enhance the immune response of the vaccinated individual.

[58] For a description of all revisions to the EUA, see Novavax COVID-19 Vaccine, Adjuvanted Letter of Authorization, October 19, 2022. This Letter of Authorization is posted on www.fda.gov.

The Agency issued the EUA for the Novavax COVID-19 Vaccine, Adjuvanted, and has subsequently amended this EUA, after a thorough evaluation of scientific data regarding the safety and effectiveness and after reaching a determination that the vaccine meets the statutory requirements under section 564 of the FD&C Act. This letter incorporates by reference the EUA Review Memoranda, which discuss these determinations, and the data upon which they were based, in detail.[59]

### ii. The Standard for Revocation of EUAs Is Not Met

Section 564(g)(2) of the FD&C Act provides the standard for revocation of an EUA. Under this statutory authority, FDA may revise or revoke an EUA if:

> (A) the circumstances described under [section 564(b)(1) of the FD&C Act] no longer exist;
> (B) the criteria under [section 564(c) of the FD&C Act] for issuance of such authorization are no longer met; or
> (C) other circumstances make such revision or revocation appropriate to protect the public health or safety.

At the outset, we note that Congress has provided FDA with discretion under section 564 of the FD&C Act and nothing in the statute *requires* FDA to *revoke* existing EUAs in any circumstance. Rather, section 564(g)(2) of the FD&C Act says that, in certain circumstances, FDA "*may* revise or revoke" an EUA.[60] The verb "may" is ordinarily permissive, particularly when the statute elsewhere uses the term "shall" to confer a mandatory duty.[61] Further underscoring FDA's discretion, the EUA statute explicitly provides that all decisions regarding EUAs are "committed to agency discretion."[62]

A permissive reading of "may" also accords with the statutory purpose of giving FDA flexibility to "permit rapid distribution of promising new drugs and antidotes in the most urgent circumstances,"[63] because it allows the Agency to permit continued distribution of EUA

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[59] FDA, Novavax COVID-19 Vaccine, Adjuvanted EUA Decision Memoranda and Addenda to Decision Memoranda, dated July 13, 2022; August 19, 2022; October 19, 2022 referred to collectively in this response as "FDA's Novavax COVID-19 Vaccine, Adjuvanted EUA Decision Memoranda and Addenda"), available at https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/novavax-covid-19-vaccine-adjuvanted.

[60] Section 564(g)(2) of the FD&C Act (emphasis added).

[61] See *Old Line Life Ins. Co. of Am. v. Garcia*, 411 F.3d 605, 614-615 (6th Cir. 2005); *Goodman v. City Prods. Corp, Ben Franklin Div.*, 425 F.2d 702, 703 (6th Cir. 1970); *Anderson v. Yungkau*, 329 U.S. 482, 485 (1947) ("[W]hen the same Rule uses both 'may' and 'shall,' the normal inference is that each is used in its usual sense—the one act being permissive, the other mandatory."); see also A. Scalia & B.A. Garner, *Reading Law: The Interpretation of Legal Texts* 112 (2012) ("The traditional, commonly repeated rule is that *shall* is mandatory and *may* is permissive. . ."). There is nothing to indicate that section 564(g)(2) of the FD&C Act departs from this ordinary meaning of "may."

[62] See section 564(i) of the FD&C Act. *See also Association of American Physicians & Surgeons v. FDA*, 2020 WL 5745974, at *3 (6th Cir. Sept. 24, 2020) (citing to section 564(i) of the FD&C Act for the proposition that "emergency-use authorizations are exempt from review under the [Administrative Procedure Act].").

[63] See 2004 U.S.C.C.A.N. S17, S18 (Statement of President Bush Upon Signing P.L. 108-276, PROJECT BIOSHIELD ACT OF 2004).

products and thereby removes the need for manufacturers to limit supply or delay seeking approval to exhaust supplies of authorized product.

FDA's EUA Guidance notes that once an EUA is issued for a product, in general, that EUA will remain in effect for the duration of the EUA declaration under which it was issued, "unless the EUA is revoked because the criteria for issuance . . . are no longer met or revocation is appropriate to protect public health or safety (section 564(f),(g) [of the FD&C Act])."[64] Thus, in this section, we assess whether any of the statutory conditions under which FDA may revoke an EUA are met, namely: (1) whether the circumstances described under section 564(b)(1) of the FD&C Act no longer exist, (2) whether the criteria for their issuance under section 564(c) of the FD&C Act are no longer met, and (3) whether other circumstances make a revision or revocation appropriate to protect the public health or safety.

**a. Circumstances Described under Section 564(b)(1) of the FD&C Act Continue to Exist**

Section 564(b)(1) of the FD&C Act describes the circumstances under which the HHS Secretary may declare that circumstances exist justifying the issuance of EUAs. As explained above, on February 4, 2020, pursuant to section 564(b)(1)(C) of the FD&C Act (21 U.S.C. § 360bbb-3(b)(1)(C)), the Secretary of HHS determined 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 the virus that causes COVID-19.[65] On the basis of such determination, on March 27, 2020, the Secretary then declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to section 564(b)(1) of the FD&C Act (21 U.S.C. § 360bbb-3(b)(1)).[66]

Based on this declaration and determination, under section 564(c) of the FD&C Act (21 U.S.C. § 360bbb-3(c)), FDA may issue an EUA during the COVID-19 pandemic after FDA concludes that the statutory requirements provided in section 564(c) are met. Section 564(b)(2) sets forth the statutory standard for termination of an EUA declaration. An EUA declaration remains in place until the earlier of: (1) a determination by the HHS Secretary that the circumstances that precipitated the declaration have ceased (after consultation as appropriate with the Secretary of Defense) or (2) a change in the approval status of the product such that the authorized use(s) of the product are no longer unapproved.

The Petitions do not demonstrate, nor do the Petitions assert any claim(s), that the circumstances described under section 564(b)(1) no longer exist. The Petitions therefore have not shown that there are grounds for revoking the EUA for any of the Authorized COVID-19 Vaccines on the basis of section 564(g)(2)(A) (i.e., on the basis that the circumstances described under section 564(b)(1) no longer exist).

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[64] EUA Guidance at 28.
[65] HHS, Determination of Public Health Emergency, 85 FR 7316, February 7, 2020, https://www.federalregister.gov/documents/2020/02/07/2020-02496/determination-of-public-health-emergency.
[66] COVID-19 EUA Declaration.

### b. The Criteria for the Issuance of the EUA Continue to Be Met

Section 564(g)(2)(B) of the FD&C Act provides that FDA may revise or revoke an authorization if the criteria for issuance of the authorization under section 564(c) of the FD&C Act are no longer met. This section describes why the Petition has not demonstrated that the criteria under section 564(c) of the FD&C Act are no longer met with respect to any of the Authorized COVID-19 Vaccines and why, therefore, FDA is not revoking the EUAs for any of the Authorized COVID-19 Vaccines under the authority in section 564(g)(2)(B) of the FD&C Act.

#### 1. Serious or Life-Threatening Disease or Condition

As explained above in section II.C of this letter, section 564(c)(1) of the FD&C Act requires that, for an EUA to be issued for a medical product, the "agent[s] referred to in [the HHS Secretary's EUA declaration] can cause a serious or life-threatening disease or condition." FDA has concluded that SARS-CoV-2, which is the subject of the EUA declaration, meets this standard.

The SARS-CoV-2 pandemic continues to present an extraordinary challenge to global health and, as of February 10, 2023, has caused more than 672 million cases of COVID-19 and claimed the lives of more than 6.85 million people worldwide.[67] In the United States, as of February 9, 2023, more than 102 million cases and over 1.1 million deaths have been reported to the Centers for Disease Control and Prevention (CDC).[68] On January 31, 2020, the Secretary of HHS declared a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS, and the U.S. President declared a national emergency in response to COVID-19 on March 13, 2020. Additional background information on the SARS-CoV-2 virus and COVID-19 pandemic may be found in FDA's EUA decision memoranda regarding the Authorized COVID-19 Vaccines.[69]

As explained above, FDA has concluded that SARS-CoV-2 can cause a serious or life-threatening disease or condition. Petitioner has not provided any data, and FDA is not aware of any data, that change the conclusion that SARS-CoV-2 can cause a serious or life-threatening disease or condition. The Petitions thus fail to establish that the criterion under section 564(c)(1) is no longer met for any of the Authorized COVID-19 Vaccines.

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[67] Johns Hopkins University School of Medicine, Coronavirus Resource Center, https://coronavirus.jhu.edu/map.html (accessed February 10, 2023).
[68] CDC, COVID Data Tracker, https://covid.cdc.gov/covid-data-tracker/#datatracker-home (accessed February 10, 2023).
[69] See FDA's Pfizer-BioNTech COVID-19 Vaccine EUA Decision Memoranda and Addenda, FDA's Moderna COVID-19 Vaccine EUA Decision Memoranda and Addenda, FDA's Janssen COVID-19 Vaccine EUA Decision Memoranda and Addenda, and FDA's Novavax COVID-19 Vaccine, Adjuvanted EUA Decision Memoranda and Addenda.

### 2. Evidence of Effectiveness

Section 564(c)(2)(A) of the FD&C Act requires that, for an EUA to be issued for a medical product, FDA must conclude based on the totality of scientific evidence available to the Secretary, including data from adequate and well-controlled trials, if available, it is reasonable to believe that the product may be effective to prevent, diagnose, or treat such serious or life-threatening disease or condition that can be caused by SARS-CoV-2.

FDA has determined that based on the totality of scientific evidence available, including data from adequate and well-controlled trials as available, it is reasonable to believe that the Authorized COVID-19 Vaccines may be effective to prevent COVID-19. The basis for these determinations are explained in detail in FDA's decision memoranda regarding the EUAs for the Authorized COVID-19 Vaccines.[70]

Petitioner has not provided any data or raised concerns about the adequacy of data relied upon to authorize EUAs for the Authorized Covid-19 vaccines. Furthermore, the Petitions fail to provide information, nor is FDA aware of any information, that overcomes FDA's determinations that the Authorized COVID-19 Vaccines may be effective to prevent COVID-19 when administered as specified in the corresponding EUA. The Petitions fail to establish that the criterion under section 564(c)(2)(A) is no longer met for any of the Authorized COVID-19 Vaccines. We discuss the Petitions' claims about effectiveness in the sections below.

### 3. Benefit-Risk Analysis

Section 564(c)(2)(B) of the FD&C Act requires that, for an EUA to be issued for a medical product, FDA must conclude that "the known and potential benefits of the product, when used to diagnose, prevent, or treat [the identified serious or life-threatening disease or condition], outweigh the known and potential risks of the product." FDA authorized the Authorized COVID-19 Vaccines for emergency use after reaching a determination that, among other things, the known and potential benefits of the vaccines, when used to prevent COVID-19 in the authorized populations, outweigh their known and potential risks.[71]

In this section, we address Petitioner's arguments relevant to the benefits and risks of the Authorized COVID-19 Vaccines and explain why they do not alter the Agency's determination

[70] See FDA's Pfizer-BioNTech COVID-19 Vaccine EUA Decision Memoranda and Addenda, FDA's Moderna COVID-19 Vaccine EUA Decision Memoranda and Addenda, FDA's Janssen COVID-19 Vaccine EUA Decision Memoranda and Addenda, and FDA's Novavax COVID-19 Vaccine, Adjuvanted EUA Decision Memoranda and Addenda.

[71] For an extensive discussion of FDA's analysis of the clinical trial data regarding the risks and benefits of the Authorized COVID-19 Vaccines, see FDA's Pfizer-BioNTech COVID-19 Vaccine EUA Decision Memoranda and Addenda, FDA's Moderna COVID-19 Vaccine EUA Decision Memoranda and Addenda, FDA's Janssen COVID-19 Vaccine EUA Decision Memoranda and Addenda, and FDA's Novavax COVID-19 Vaccine, Adjuvanted EUA Decision Memoranda and Addenda.

that the criterion in section 564(c)(2)(B) is satisfied. For the reasons discussed in this section, the criterion under section 564(c)(2)(B) of the FD&C Act continues to be met.

***Petitioner's Statements Regarding Effectiveness of Vaccines Against Mutated Viruses***

Petitioner claims that "[t]he general problem with all [COVID-19 Vaccines] is the mutation rate of the virus itself[,] [b]ecause of the mutation rate of the virus, the efficacy of the Covid 19 vaccines drops very quickly over time."[72] Petitioner further asserts that "[t]he benefit of the use of Covid 19 vaccines are wiped out once the viral mutations involved reduce the efficacy of the vaccines administered."[73] The Petitioner asserts that "given the high mutation rate of COVID 19…no existing Covid 19 vaccines should ever be authorized or used in the United States or anywhere else in the world, unless they are proven to substantially stop infection, viral mutation, and transmission of the Virus."[74] Petitioner also references online materials regarding the lack of efficacy of COVID-19 vaccines.[75]

First, to the extent that the Petition questions the effectiveness of Authorized COVID-19 Vaccines because these vaccines do not "substantially stop infection…and transmission of the Virus," it is important to note that the Authorized COVID-19 Vaccines are authorized to prevent COVID-19, not to prevent SARS-CoV-2 infection or transmission. Additionally, a vaccine does not need to be 100% effective in preventing the target disease to meet the licensure or EUA standard. It is expected that some vaccinated individuals will contract the target disease despite having been vaccinated against it. No FDA licensed or authorized vaccine is 100% effective, but scientific data have nevertheless demonstrated that vaccinations have been a very effective approach to protecting the public's health in the United States.[76] Similarly, a COVID-19 vaccine need not be 100% effective in preventing COVID-19, or close to 100% effective in doing so, in order to have a significant positive effect in altering the course of the COVID-19 pandemic and for the known and potential benefits to outweigh the known and potential risks.

In addition, we note that throughout the pandemic, FDA has made decisions based on the best available science as the SARS-CoV-2 virus has continued to evolve. The Pfizer-BioNTech COVID-19 Vaccine and Moderna COVID-19 Vaccine are monovalent mRNA vaccines based on the original Wuhan strain. The Pfizer-BioNTech Covid-19 Vaccine, Bivalent and the Moderna COVID-19 Vaccine, Bivalent, are bivalent vaccines that have an mRNA component that corresponds to the original Wuhan SARS-CoV-2 strain and an mRNA component corresponding

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[72] Petition at 4.
[73] *Id.* at 5.
[74] *Id.* at 2.
[75] To support this claim, Petitioner references an online article (NOT a vaccine: Pfizer's own data shows that covid jabs produce NEGATIVE efficacy within 30 days, VaccinesNews (Oct. 6, 2022), https://www.vaccines.news/2022-10-06-pfizer-data-covid-vaccines-negative-efficacy-30days html) that claims that the Pfizer COVID-19 Vaccine causes "Vaccine-induced AIDS…[and] destroy[s] natural immunity…." This article provides no data to support these claims. Petition at 8.
[76] FDA, Vaccine Safety Questions and Answers, last updated March 2018, https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/vaccine-safety-questions-and-answers.

to the Omicron variant BA.4 and BA.5 lineages of SARS-CoV-2. The Janssen COVID-19 Vaccine is a monovalent viral vector vaccine expressing the SARS-CoV-2 spike protein, and the Novavax COVID-19 Vaccine, Adjuvanted is a monovalent protein subunit vaccine that contains the SARS-CoV-2 spike protein and Matrix-M adjuvant. The recently and currently circulating SARS-CoV-2 variants harbor mutations in the S protein that confer at least partial antigenic escape from vaccine-elicited immunity. Petitioner has not shown that the Authorized COVID-19 Vaccines fail to retain effectiveness, especially effectiveness against severe outcomes.

Results from post-authorization observational studies that have assessed the effectiveness of primary vaccination with monovalent COVID-19 vaccines have shown decreased effectiveness against certain variants (notably Omicron) and waning effectiveness over time.[77] Data have shown that COVID-19-associated hospitalization rates among adults were lowest among those adults who had received a booster dose or additional dose as compared to those vaccinated with a primary series.[78]

Additionally, Petitioner references various articles and online information regarding immune imprinting.[79] The Petitioner uses referenced articles and online information related to immune imprinting to argue that use of the bivalent COVID-19 vaccines are ineffective. However, the mechanism of imprinting and its effect on the subsequent response to vaccination is not well understood and requires further study. The available observational effectiveness data strongly

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[77] See Andrews et al., Covid-19 Vaccine Effectiveness Against the Omicron (B.1.1.529) Variant, NEJM (Apr. 21, 2022), 386: 1532-1546, DOI: 10.1056/NEJMoa2119451; Taylor et al., COVID-19–Associated Hospitalizations Among Adults During SARS-CoV-2 Delta and Omicron Variant Predominance, by Race/Ethnicity and Vaccination Status — COVID-NET, 14 States, July 2021–January 2022, Morb Mortal Wkly Rep. (Mar. 25, 2022), 71(12): 466–473, DOI: https://www.cdc.gov/mmwr/volumes/71/wr/mm7112e2 htm.

[78] See Taylor et al., COVID-19–Associated Hospitalizations Among Adults During SARS-CoV-2 Delta and Omicron Variant Predominance, by Race/Ethnicity and Vaccination Status — COVID-NET, 14 States, July 2021–January 2022, 2022.

[79] Petitioner states that "[i]mmune imprinting involves problems with an imbalanced immune system where the immune systems involved decide to go with say an Omicron booster shot created B memory cell rather than creating a newer and correct B memory cell for the current infection." Amended Petition at 4. Petitioner states that "[i]n the case of Omicron being the current main Covid 19 variant and immune imprinting the fact that we are currently dealing with fast antigenic drift rather than antigenic shift is not a detractor to this petition" and "[w]ith immune imprinting a situation where the immune system is acting with mismatched B and T cells at least initially where the virus continues to increase in virility[,] I am judging a 2 to one increase in the death count involved with vaccine users because of this mismatch." Id. In an attachment to the Amended Petition (Amended Petition Attachment), Petitioner includes a link to a journal article (Wheatley et al., Immune imprinting and SARS-CoV-2 vaccine design, Trends Immunol. 2021 Nov; 42(11): 956–959. doi: 10.1016/j.it.2021.09.001) presenting the authors' hypotheses regarding immune imprinting and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines. Petitioner also includes a link to an online opinion piece (Brozak, St., Marfuggi, R., Lessons from earlier pandemics: Vaccine panel must discuss imprinting among infants and toddlers, StatNews (June 13, 2022), https://www.statnews.com/2022/06/13/lessons-from-earlier-pandemics-vaccine-panel-must-discuss-imprinting-among-infants-and-toddlers/) that mentions a then upcoming CDC meeting in June 2022 to discuss COVID-19 vaccination to infants and toddlers and notes that the "issue of imprinting may not be on the agenda." This opinion piece also references the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC). Additionally, Petitioner includes links to online reports, by Children's Health Defense, of a roundtable discussion titled- "COVID-19 Vaccines: What They Are, How They Work and Possible Causes of Injuries." With regards to immune imprinting, these online materials do not demonstrate that the authorized bivalent COVID-19 vaccines fail to meet the "may be effective" standard.

suggest that bivalent booster immunization provides additional protection against symptomatic infection, emergency department/urgent care visits, and hospitalization.[80] As noted above, on August 31, 2022, FDA amended the EUAs for the Pfizer COVID-19 Vaccine and Moderna COVID-19 Vaccine to authorize the use of bivalent vaccines sponsored by Pfizer and Moderna as single booster doses. The EUAs have been subsequently amended to authorize the use of the Pfizer COVID-19 Vaccine, Bivalent and the Moderna COVID-19 Vaccine, Bivalent as single booster doses for younger populations.

Therefore, to the extent that the Petition asserts that the risk-benefit criterion for issuance of the EUAs is no longer met due to viral mutations, Petitioner fails to demonstrate that the known and potential benefits of the Authorized COVID-19 Vaccines have decreased such that they no longer outweigh the known and potential risks. The totality of the available scientific evidence continues to support our determination that the known and potential benefits of the Authorized COVID-19 Vaccines outweigh their known and potential risks. The Petition fails to prove otherwise.

***Petitioner's Statements Regarding Vaccine Use Increasing Virus Mutation Rate***

Petitioner claims that "the immune escape of the virus and mutation rate of the virus has the world's human population reliving repeated rounds of Covid 19 variant infections year over year."[81] Petitioner claims that "[t]wo key evaluations of viral mutation are antigenic drift and antigenic shift" and asserts that "[t]he antigenic shift without vaccine use should normally be 2000 years with an average virus."[82] Petitioner further asserts that "[w]hen combined with the fairly high risk factor vs the benefit of each vaccine shot, every use of a Covid 19 vaccine or vaccine booster shot has a greater chance to produce mutation and negative side effects, than it has to stop the transmission of the virus."[83] Additionally, Petitioner asserts that "vaccines not only cause many of the mutations but also the pandemic gets reinvigorated over and over again probably for decades because the use of Covid 19 vaccines."[84]

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[80] See Link-Gelles et al., Effectiveness of Bivalent mRNA Vaccines in Preventing Symptomatic SARS-CoV-2 Infection - Increasing Community Access to Testing Program, United States, September–November 2022, MMWR Morb Mortal Wkly Rep 2022;71:1526–1530. https://www.cdc.gov/mmwr/volumes/71/wr/mm7148e1.htm.; Tenforde et al., Early Estimates of Bivalent mRNA Vaccine Effectiveness in Preventing COVID-19–Associated Emergency Department or Urgent Care Encounters and Hospitalizations Among Immunocompetent Adults - VISION Network, Nine States, September–November 2022, MMWR Morb Mortal Wkly Rep 2022;71:1616–1624. https://www.cdc.gov/mmwr/volumes/71/wr/mm715152e1 htm#:~:text=%3D%2055%20years).-,VE%20of%20a%20bivalent%20booster%20dose%20(after%202%2C%203%2C,%25)%20compared%20with%20receipt%20of.; Surie et al., 2022 Early Estimates of Bivalent mRNA Vaccine Effectiveness in Preventing COVID-19–Associated Hospitalization Among Immunocompetent Adults Aged ≥65 Years — IVY Network, 18 States, September 8–November 30, 2022, MMWR Morb Mortal Wkly Rep 2022;71:1625–1630. https://www.cdc.gov/mmwr/volumes/71/wr/mm715152e2 htm.; Arbel et al., 2023 Effectiveness of the Bivalent mRNA Vaccine in Preventing Severe COVID-19 Outcomes: An Observational Cohort Study, Lancet, (preprint) http://dx.doi.org/10.2139/ssrn.4314067.

[81] Petition at 4.

[82] *Id.*

[83] *Id.*

[84] *Id.* at 5-6.

In support of this proposition, Petitioner references online materials which seem to imply that COVID-19 vaccination efforts are driving virus mutation and the selection of more infectious variants.[85] These materials appear to represent speculation and do not provide scientific evidence that "immune escape dramatically increases the mutation rate of the Covid 19 virus…helps render the value of the use of Covid 19 vaccines not only worthless but that there is a big negative value from the use of [these vaccines] since the virus will have a bigger longer term impact from more variants over time from the virus."[86] The information provided in the Petition does not undermine the totality of the scientific evidence supporting the authorization of the vaccines.

***Petitioner's Claims Relating to Temporary Antibodies***

Petitioner makes several claims related to temporary antibodies generated by COVID-19 Vaccines. Petitioner claims that vaccines such as the Authorized COVID-19 Vaccines offer "partial defense against illnesses like Covid 19"[87] because "most childhood only generate B memory cells and temporary antibodies...no T cells are being produced."[88] Petitioner further asserts that COVID-19 Vaccines "do not produce a balanced immune system memory like the human immune system does in a normal reaction to a typical illness involving pathogens…[t]he T cells only come about after infection of the pathogens"[89, 90]

As noted in FDA's guidance, *Development and Licensure of Vaccines to Prevent COVID-19*,[91] understanding of SARS-CoV-2 immunology, and specifically vaccine immune responses that might predict protection against COVID-19, is currently limited and evolving.[92] While FDA agrees that greater understanding of the role of T-cell response in protection against COVID-19 could be useful to the scientific and public health community, Petitioner has not provided information showing that the authorized COVID-19 vaccines do not induce a T-cell response and that this asserted lack of T-cell response results in inadequate protection.

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[85] Petitioner references online materials that appear to be video interviews with Dr. Geert Vanden Bossche on internet programs. Petition at 6. *See* The Dangers of Mass Vaccination During Pandemics – Dr. Geert Vanden Bossche Explains Why, Aga Wilson Show (October 9, 2022), https://newsvoice.se/2022/10/dr-geert-vanden-bossche-mass-vaccination/ and Are Vaccines Driving Virus Mutation? Good Morning CHD (November 5, 2022), https://live.childrenshealthdefense.org/chd-tv/shows/good-morning-chd/are-vaccines-driving-virus-mutation/.

[86] Petition at 6.

[87] *Id.* at 7.

[88] *Id.* at 6.

[89] *Id.* at 6-7.

[90] Petitioner also references a journal article (Gilbert, T-cell-inducing vaccines-what's the future, Immunology. 2012 Jan; 135(1): 19–26. doi: 10.1111/j.1365-2567.2011.03517.x) discussing clinical research regarding T-cell and hypothesizing on future T-cell-inducing vaccines. Petition 6. This article does not support any conclusion questioning the efficacy or risk/benefit analysis of Authorized COVID-19 Vaccines.

[91] See Vaccine Development and Licensure Guidance, https://www.fda.gov/media/139638/download.

[92] Vaccine Development and Licensure Guidance at 9.

***Petitioner's Assertions Concerning Adverse Events Reported Through VAERS***

Petitioner asserts that "[o]n the negative side of use of the Covid 19 vaccines there are deaths directly caused by the vaccines and serious injuries caused by the vaccines" and claims that "every use of a Covid 19 vaccine or vaccine booster shot has a greater chance to produce mutations and negative side effects, than it has to stop the transmission of the virus."[93] To support this assertion, Petitioner relies on adverse events reported to the Vaccine Adverse Event Reporting System (VAERS) to conduct calculations in the Petition, using his own estimates and methodology, to suggest that the COVID-19 vaccines lead to "human years of suffering."[94] The Petition also references an online article discussing VAERS.[95]

FDA is monitoring the safety of authorized and approved COVID-19 vaccines through both passive and active safety surveillance systems. FDA is doing so in collaboration with the CDC, the Centers for Medicare and Medicaid Services (CMS), the Department of Veterans Affairs (VA), and other academic and large non-government healthcare data systems.

There are extensive vaccine safety surveillance efforts in place, including VAERS, for COVID-19 vaccines.[96] VAERS is a national passive surveillance vaccine safety database that receives unconfirmed reports of possible adverse events following the use of a vaccine licensed or authorized in the United States. Passive surveillance is defined as unsolicited reports of adverse events that are sent to a central database or health authority. In the United States, these are received and entered into VAERS, which is co-managed by FDA and CDC. In the current pandemic, these reports are being used to monitor the occurrence of both known and unknown adverse events, as providers of COVID-19 vaccines are required to report serious adverse events to VAERS. As part of FDA and CDC's multi-system approach to post-licensure and post-authorization vaccine safety monitoring, VAERS is designed to rapidly detect unusual or unexpected patterns of adverse events. VAERS reports generally cannot be used to determine if a vaccine caused or contributed to an adverse event or illness. If the VAERS data suggest a

[93] Petition at 4.

[94] In the Amended Petition, Petitioner updates these calculations, again using his own estimates and methodology, to state that while the calculations in the original petition showed that the COVID-19 vaccines cause "over 10 times more harm then [sic] benefit in human years of life gained, lost, or impaired equivalent" the updated calculations show "that harm versus benefit to at least 60 to 1..." Amended Petition at 2 and 3. Petitioner states that "[v]accines should only be authorized for use when the originally evaluated benefits vs harm of the vaccines are about 1000 to 1 respectfully in initial trials of the vaccines." Id. at 3. In support of these new calculations, Petitioner references an attachment submitted with the amended petition (Amended Petition Attachment) in which Petitioner has included links to various online materials that Petitioner claims has led Petitioner to "increase the harm to benefit at least another 3 fold." Id. at 4.

[95] Petition at 5 referencing: 1.4 Million Adverse Events After COVID Vaccines Reported to VAERS, Canadian Woman Dies 7 Minutes After Bivalent Booster Shot, Children's Health Defense (September 23, 2022), https://childrenshealthdefense.org/defender/vaers-covid-vaccines-canadian-woman-dies-bivalent-booster-shot/?utm_source=salsa&eType=EmailBlastContent&eId=85fe9c29-0c51-470e-a80c-39f40e1003f3.

[96] FDA, COVID-19 Vaccine Safety Surveillance, https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/covid-19-vaccine-safety-surveillance.

possible link between an adverse event and vaccination, the relationship may be further studied in a controlled fashion.[97]

VAERS is not designed to assess causality. It is often difficult to determine with certainty if a vaccine caused or contributed to causing an adverse event reported to VAERS. Many events that occur after vaccination can happen by chance alone. FDA draws upon multiple sources of data and medical and scientific expertise to assess the potential strength of association between a vaccine, including COVID-19 vaccines, and a possible adverse event.

The monitoring and analysis of VAERS reports typically includes ongoing screening of incoming serious reports for COVID-19 vaccines (including collection of follow-up medical information and in-depth medical review of certain adverse event reports of interest), statistical data mining techniques, and epidemiological analysis. If VAERS monitoring suggests that a vaccine might be causing a health problem, additional scientifically rigorous studies or investigations can be performed by FDA and CDC. When there is sufficient evidence for a potential safety concern, we may proceed to conduct large studies, and we may coordinate with our federal, academic, and private partners to further assess the potential risk after vaccination.

VAERS reports provide a very important tool in monitoring vaccine safety, but as discussed above, these reports alone cannot be used to determine if a vaccine caused or contributed to an adverse event or illness.[98] For example, under the EUAs for the Authorized COVID-19 Vaccines, unlike for previously approved vaccines, vaccination providers are required to report to VAERS serious adverse events following vaccination with the COVID-19 vaccines "irrespective of attribution to vaccination" and regardless of how long after vaccination the adverse event occurs.[99]

It is also important to consider other factors that have contributed to the volume of VAERS reports. First, we note that a large number of COVID-19 vaccine doses have been administered in the United States and that certain adverse event reporting by vaccination providers is required for all currently authorized COVID-19 vaccines. As of February 9, 2023, over 670,000,000

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[97] FDA, VAERS Overview, https://www fda.gov/vaccines-blood-biologics/vaccine-adverse-events/vaers-overview.
[98] VAERS Data Disclaimer, https://vaers.hhs.gov/data html.
[99] See, e.g., Pfizer-BioNTech COVID-19 Fact Sheets for Healthcare Providers Administering Vaccine (Vaccination Providers), Section 8, Requirements and Instructions for Reporting Adverse Events and Vaccine Administration Errors, https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccines#additional; Moderna COVID-19 Fact Sheets for Healthcare Providers Administering Vaccine (Vaccination Providers), Section 8, Requirements and Instructions for Reporting Adverse Events and Vaccine Administration Errors, https://www fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccines#additional; Janssen COVID-19 Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers), Section 8, Requirements and Instructions for Reporting Adverse Events and Vaccine Administration Errors, https://www.fda.gov/media/146304/download; Novavax COVID-19 Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers), Section 8, Requirements and Instructions for Reporting Adverse Events and Vaccine Administration Errors, https://www.fda.gov/media/159897/download.

doses of authorized COVID-19 vaccines have been administered in the United States.[100] Another contributing factor is the v-safe system,[101] which is a CDC smartphone-based active-surveillance system, developed for the COVID-19 vaccination program, in which participants who have been vaccinated may voluntarily enroll. V-safe sends text messages and web surveys to participants who can report side effects following receipt of a COVID-19 vaccine. If a participant indicates through the v-safe surveys that he or she required medical care at any time, CDC calls the participant to complete a report through VAERS. This system is unique to COVID-19 vaccines and may be contributing to the number of VAERS reports submitted for the COVID-19 Vaccines.

Finally, an additional potential factor is the concept of "stimulated reporting."[102] Because of extensive media coverage and awareness of the public health emergency—and of COVID-19 vaccines and their reported side effects–vaccine recipients, health care providers, and others may be more likely to report adverse events for the COVID-19 vaccines than for other vaccines that have been widely available for longer periods of time. Although VAERS is not designed to assess causality, FDA and CDC actively monitor VAERS reports and engage in additional studies or investigations if VAERS monitoring suggests that a vaccine might be causing a health problem.

In making our authorization decisions, we have considered information obtained through VAERS. Accordingly, FDA already accounts for the information received through VAERS in assessing the known and potential risks of the authorized vaccines. However, Petitioner's assertions fail to take the factors outlined above into account. VAERS reports alone cannot be used to determine if a vaccine caused or contributed to an adverse event or illness, and Petitioner's reference to the number of VAERS reports fails to take into account there are a number of contributing factors to the volume of VAERS reports. For the reasons discussed above, Petitioner's assertions regarding adverse events do not change FDA's conclusion that the known and potential benefits of the Authorized COVID-19 Vaccines outweigh their known and potential risks.

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[100] CDC, COVID Data Tracker, COVID-19 Vaccinations in the United States, https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total (accessed February 16, 2023).
[101] CDC, v-safe Overview, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe html.
[102] "Like all spontaneous public health reporting systems, VAERS has limitations. VAERS is subject to reporting bias, including underreporting of adverse events – especially common, mild ones– and stimulated reporting, which is elevated reporting that might occur in response to intense media attention and increased public awareness, such as during the 2009 H1N1 pandemic influenza vaccination program" Shimabukuro et al., Safety monitoring in the Vaccine Adverse Event Reporting System (VAERS), Vaccine (Nov. 4, 2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4632204/. See also Vellozzi et al., Adverse Events Following Influenza A (H1N1) 2009 Monovalent Vaccines Reported to the Vaccine Adverse Event Reporting System, United States, October 1, 2009–January 31, 2010, Vaccine (Oct. 21, 2010), https://www.sciencedirect.com/science/article/pii/S0264410X10013319.

***Petitioner's Statements Regarding Deaths***

Petitioner also claims that "a lot of deaths have occurred since the start of Covid 19 vaccine development" and states that "[d]eaths are now higher for those vaccinated for Covid 19 then unvaccinated."[103] In support of this statement, Petitioner references an online article[104] reporting on CDC data regarding the rates of COVID-19 related deaths by age group and vaccination status and booster dose.

As noted by the CDC, "several factors have led to changing patterns of COVID-19 morbidity and mortality over the course of the pandemic, including the introduction and widespread availability of COVID-19 vaccines, high population prevalence of infection-induced immunity, increased availability of effective COVID-19 outpatient treatment, and changes in the SARS-CoV-2 virus itself."[105] CDC data demonstrates that following a rapid reduction in overall U.S. COVID-19–related mortality rate in March 2022, COVID-19–related mortality rates remained relatively stable from April through September 2022.[106]

Petitioner's claim that "[d]eaths are now higher for those vaccinated for Covid 19 then unvaccinated" is not supported by the article nor demonstrated by the data. First, as noted in the online article, a large majority of the American public have received at least a primary series of COVID-19 vaccines, "so it makes sense that vaccinated people are making up a greater share of fatalities."[107] The article also notes that "[i]ndividuals at greatest risk of dying …such as the

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[103] *Id.* at 9. Petitioner references an online article (SECRET CDC REPORT: Since the launch of Operation Warp Speed, at least 1.1 million Americans have "died suddenly" (Dec. 2, 2022), https://www.naturalnews.com/2022-12-02-operation-warp-speed-millions-americans-died-suddenly html#) that suggests excess deaths since the authorization of COVID-19 vaccines are related to vaccination. The CDC continues to monitor provisional death counts for Coronavirus Disease 2019 (COVID-19), including excess death data. (see https://www.cdc.gov/nchs/covid19/mortality-overview.htm). As explained by the CDC, excess deaths "are typically defined as the difference between the observed numbers of deaths in specific time periods and expected numbers of deaths in the same time periods." (see https://www.cdc.gov/nchs/nvss/vsrr/covid19/excess_deaths.htm). The CDC further states that "excess deaths with and without COVID-19 — can provide insight about how many excess deaths are identified as due to COVID-19, and how many excess deaths are reported as due to other causes of death" and "[t]hese deaths could represent misclassified COVID-19 deaths, or potentially could be indirectly related to the COVID-19 pandemic (e.g., deaths from other causes occurring in the context of health care shortages or overburdened health care systems)." Id. Petitioner provides no data or evidence that 1.1 million excess deaths are caused by COVID-19 vaccinations. Additionally, Petitioner claims that "deaths related to use of vaccines are being purposely hidden by the government" and cites to an online article (Massachusetts Death Certificates Show Excess Mortality Could Be Linked to COVID Vaccines, Children's Health Defense Fund (Nov. 22, 2022), https://childrenshealthdefense.org/defender/massachusetts-death-certificates-excess-mortality-covid-vaccines/?utm_source=salsa&eType=EmailBlastContent&eId=ac297e18-901a-4ab3-b849-4355e5f749d1) to support this claim. This article contains unpublished information and is speculative.

[104] Covid is no longer mainly a pandemic of the unvaccinated, Washington Post (Nov. 23, 2022), https://www.washingtonpost.com/politics/2022/11/23/vaccinated-people-now-make-up-majority-covid-deaths/.

[105] CDC, COVID-19 Data Review: Update on COVID-19–Related Mortality (last updated November 16, 2022), https://www.cdc.gov/coronavirus/2019-ncov/science/data-review/index.html.

[106] *Id.*

[107] Covid is no longer mainly a pandemic of the unvaccinated, Washington Post (Nov. 23, 2022), https://www.washingtonpost.com/politics/2022/11/23/vaccinated-people-now-make-up-majority-covid-deaths/.

elderly, are also more likely to have received the shots."[108] Also, when the data are adjusted to account for factors such as age, vaccinated groups are at a lower risk of dying from COVID-19 than the unvaccinated, as reported in the online article.[109]

Petitioner's assertions regarding deaths from COVID-19 amongst vaccinated individuals fail to demonstrate that the known and potential risks of the Authorized COVID-19 Vaccines outweigh known and potential benefits.

***Petitioner's Statements Regarding Other Risks***

Throughout the Petition, Petitioner makes several other claims regarding other risks that Petitioner asserts are associated with COVID-19 vaccines. First, Petitioner asserts that "[mRNA] vaccines are noted for often causing long Covid conditions without actually catching Covid 19 and also for subclinical myocarditis where the incidence of subclinical myocarditis is hundreds of times more common than clinical myocarditis."[110] Petitioner also references online articles to support the assertion that certain fatal heart conditions are caused by COVID-19 vaccines.[111] The Petition provides no evidence or data to support the claim regarding the magnitude of the rate of subclinical myocarditis relative to myocarditis. FDA has carefully considered the risks of myocarditis and pericarditis for vaccine recipients and has concluded that the chance of occurrence is very low and, based on the available data, the known and potential benefits of the Authorized COVID-19 Vaccines outweigh their known and potential risks.[112] In addition, we note that for the authorized and approved COVID-19 vaccines, the Fact Sheets for Healthcare Providers Administering Vaccine (Vaccination Providers) include a warning about the risks of myocarditis and pericarditis, and the Fact Sheets for Recipients and Caregivers include information about myocarditis and pericarditis.[113]

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[108] *Id.*
[109] *Id.*
[110] *Id.* at 8.
[111] *Id.* at 9 referencing: Autopsies Show COVID Vaccine Caused Fatal Cardiac Condition in Some People, Dec. 5, 2022, https://childrenshealthdefense.org/defender/autopsies-covid-vaccine-fatal-myocarditis-et/?utm_source=salsa&eType=EmailBlastContent&eId=8e1e0a17-1930-48d4-a496-ba86bff32f51; COVID Vaccines Were a Shot in the Dark and Mortality Statistics Prove It, Dec. 5, 2022, https://childrenshealthdefense.org/defender/covid-vaccines-mortality-statistics-cola/?utm_source=salsa&eType=EmailBlastContent&eId=8e1e0a17-1930-48d4-a496-ba86bff32f51.
[112] For additional information, see FDA's Pfizer-BioNTech COVID-19 Vaccine EUA Decision Memoranda and Addenda (available at: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccines), FDA's Moderna COVID-19 Vaccine EUA Decision Memoranda and Addenda (https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccines), FDA's Novavax COVID-19 Vaccine, Adjuvanted EUA Decision Memoranda and Addenda (https://www fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/novavax-covid-19-vaccine-adjuvanted), and FDA's Janssen COVID-19 Vaccine EUA Decision Memoranda and Addenda (https://www fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine).
[113] See e.g.: FDA, Pfizer-BioNTech COVID-19 Vaccine Fact Sheets for Healthcare Providers Administering Vaccine and Recipients and Caregivers available at: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccines#additional.; FDA, Moderna

The Petition does not provide any new data or information regarding the risk of myocarditis. Petitioner's reference to this risk, which has been carefully considered by FDA when authorizing for emergency use the Authorized COVID-19 Vaccines does not alter FDA's conclusions with respect to the benefits and risks of these vaccines.

Petitioner also asserts that "Covid 19 can lead to blood clotting."[114] Because Petitioner references a study published in *BMJ* comparing the risk of thrombosis with thrombocytopenia syndrome or thromboembolic events associated with various COVID-19 vaccines (produced by Oxford-AstraZeneca, Pfizer-BioNTech, Moderna, or Janssen), we assume Petitioner is referring to a risk of thrombosis with COVID-19 vaccines.[115] The *BMJ* study cited by the Petitioner found an increased risk of venous thrombosis with thrombocytopenia syndrome (TTS) after a first dose of the Oxford-AstraZeneca vaccine compared with the Pfizer-BioNTech COVID-19 Vaccine and a trend towards an increased risk of venous thrombosis with TTS after the Janssen COVID-19 Vaccine compared with the Pfizer-BioNTech COVID-19 Vaccine. FDA has not authorized or approved a COVID-19 vaccine sponsored by Oxford-AstraZeneca. FDA has authorized the Janssen COVID-19 Vaccine and on May 5, 2022, FDA limited the use of the Janssen COVID-19 Vaccine to individuals 18 years of age and older for whom other authorized or approved COVID-19 vaccines are not accessible or clinically appropriate, and to individuals 18 years of age and older who elect to receive the Janssen COVID-19 Vaccine because they would otherwise not receive a COVID-19 vaccine. FDA's decision accounted for the risk of TTS, a syndrome of rare and potentially life-threatening blood clots in combination with low levels of blood platelets with onset of symptoms approximately one to two weeks following administration of the Janssen COVID-19 Vaccine.[116]

After conducting an updated analysis, evaluation and investigation of reported cases of TTS, FDA determined the risk of TTS following administration of the Janssen COVID-19 Vaccine, warrants limiting the authorized use of the vaccine. FDA considered that individuals with TTS may rapidly deteriorate, despite prompt diagnosis and treatment, that TTS can lead to long-term and debilitating health consequences and that TTS has a high death rate. FDA also considered

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COVID-19 Vaccine Fact Sheets for Healthcare Providers Administering Vaccine and Recipients and Caregivers available at: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccines#additional.; FDA, Novavax COVID-19 Vaccine, Adjuvanted Fact Sheets for Healthcare Providers Administering Vaccine and Recipients and Caregivers available at: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/novavax-covid-19-vaccine-adjuvanted#additional.; and FDA, Janssen COVID-19 Vaccine, Fact Sheets for Healthcare Providers Administering Vaccine and Recipients and Caregivers available at: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine#:~:text=Fact%20Sheets%20(English)%20and%20FAQs.

[114] Petition at 8.

[115] Id. at 8 referencing Li et al., Comparative risk of thrombosis with thrombocytopenia syndrome or thromboembolic events associated with different covid-19 vaccines: international network cohort study from five European countries and the US, BMJ 2022, 379:e071594, doi: https://doi.org/10.1136/bmj-20'22-071594.

[116] FDA, Janssen COVID-19 Vaccine Frequently Asked Questions, last updated May 2022, https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine-frequently-asked-questions.

the availability of alternative authorized and approved COVID-19 vaccines which provide protection from COVID-19 and have not been shown to present a risk for TTS. FDA determined the known and potential benefits of the vaccine for the prevention of COVID-19 outweigh the known and potential risks for individuals 18 years of age and older for whom other authorized or approved COVID-19 vaccines are not accessible or clinically appropriate, and for individuals 18 years of age and older who elect to receive the Janssen COVID-19 Vaccine because they would otherwise not receive a COVID-19 vaccine.[117] Petitioner provides no information that would alter FDA's determination.

The Petitions do not provide any new data or information that change FDA's conclusion that the known and potential benefits of the Authorized COVID-19 Vaccines outweigh their known and potential risks for their authorized uses.

#### 4. No Alternatives

For a product to be granted an EUA, section 564(c)(3) of the FD&C Act requires that "there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating [the serious or life-threatening disease or condition]."

The Petitions do not argue for revocation of the EUAs for any of the Authorized COVID-19 Vaccines on the grounds that there is an adequate, approved, and available alternative to prevent COVID-19, nor does it provide persuasive information to support that such an alternative exists.

### c. No Other Circumstances Make a Revision or Revocation Appropriate to Protect the Public Health or Safety

As noted above, section 564(g)(2) of the FD&C Act provides that FDA may revise or revoke an EUA if circumstances justifying its issuance (under section 564(b)(1)) no longer exist, the criteria for its issuance are no longer met, or other circumstances make a revision or revocation appropriate to protect the public health or safety. The EUA guidance explains that such other circumstances may include:

> significant adverse inspectional findings (e.g., when an inspection of the manufacturing site and processes has raised significant questions regarding the purity, potency, or safety of the EUA product that materially affect the risk/benefit assessment upon which the EUA was based); reports of adverse events (number or severity) linked to, or suspected of being caused by, the EUA product; product failure; product ineffectiveness (such as newly emerging data that may contribute to revision of the FDA's initial conclusion that the product "may be effective" against a particular CBRN agent); a request from the sponsor to revoke the EUA; a material change in the risk/benefit assessment based on

[117] See FDA, Janssen COVID-19 Vaccine EUA Decision Memorandum, May 5, 2022, https://www.fda.gov/media/158318/download.

> evolving understanding of the disease or condition and/or availability of authorized MCMs; or as provided in section 564(b)(2), a change in the approval status of the product may make an EUA unnecessary.[118]

FDA determined the EUA standard is met for all of the Authorized COVID-19 Vaccines because available data demonstrated that the known and potential benefits of these vaccines, when used for their authorized uses, outweigh their known and potential risks.

FDA finds no basis in the information submitted in the Petitions to support a revocation of any of the Authorized COVID-19 Vaccines. As described above, the Petitions have not provided information demonstrating that the known and potential benefits of these vaccines are outweighed by the known and potential risks of these products. Furthermore, Petitioner has not demonstrated that other circumstances make a revision or revocation of the EUAs for any of these vaccines appropriate to protect the public health or safety. FDA therefore sees no justifiable basis upon which to take any action based on Petitioner's request regarding the Authorized COVID-19 Vaccines. Accordingly, as noted above, we deny Petitioner's request.

### iii. The Standard for Revocation of BLAs Is Not Met

As noted above, the only licensed vaccines indicated to prevent COVID-19 in any population are Comirnaty and Spikevax ("the Approved COVID-19 Vaccines"). FDA licensed these vaccines after determining that they satisfy the standards for approval in section 351(a) of the PHS Act, based on a demonstration that the products are safe, pure, and potent.[119]

The conditions for license revocation are set forth in 21 CFR 601.5. Pursuant to 21 CFR 601.5(a), a biologics license shall be revoked upon application of the manufacturer giving notice of intention to discontinue the manufacture of all products manufactured under such license or to discontinue the manufacture of a particular product for which a license is held and waiving an opportunity for a hearing on the matter.

Additionally, under 21 CFR 601.5(b), FDA must notify the licensed manufacturer of the intention to revoke the biologics license if it finds any of the following:

> (i) Authorized Food and Drug Administration employees after reasonable efforts have been unable to gain access to an establishment or a location for the purpose of carrying out the inspection required under 21 CFR 600.21,
> (ii) Manufacturing of products or of a product has been discontinued to an extent that a meaningful inspection or evaluation cannot be made,
> (iii) The manufacturer has failed to report a change as required by 21 CFR 601.12,

[118] EUA Guidance at 29.

[119] FDA's Summary Basis for Regulatory Action (SBRA) for the Comirnaty BLA, and FDA's SBRA for the Spikevax BLA, set forth the basis for these licensure decisions. These memoranda are posted on www fda.gov. We incorporate by reference the SBRA for the Comirnaty BLA and the SBRA for the Spikevax BLA.

(iv) The establishment or any location thereof, or the product for which the license has been issued, fails to conform to the applicable standards established in the license and in this chapter designed to ensure the continued safety, purity, and potency of the manufactured product,

(v) The establishment or the manufacturing methods have been so changed as to require a new showing that the establishment or product meets the requirements established in this chapter in order to protect the public health, or

(vi) The licensed product is not safe and effective for all of its intended uses or is misbranded with respect to any such use.

FDA has not identified any such circumstances described in 21 CFR 601.5(a) or (b) that would support revocation of the biologics license for Comirnaty or Spikevax, and Petitioner has provided no evidence that such circumstances exist. With respect to the criterion for revocation in 21 CFR 601.5(b)(vi) (i.e., the criterion that the licensed product is not safe and effective for all of its intended uses or is misbranded with respect to any such use), our analyses provided above of the Petitions' scientific evidence applies with equal force. For the reasons described above, the Petitions do not provide evidence that changes our conclusion regarding the benefits and risks of the vaccines that are subject to the Petitions. Specifically, the information provided in the Petitions do not change our conclusion that the benefits of the licensed vaccines outweigh the risks. Our benefit-risk assessment takes into account the evidence of the vaccines' safety and effectiveness. Therefore, the Petitions provide no basis for revocation of either Comirnaty or Spikevax. Accordingly, to the extent that Petitioner's request for FDA to revoke authorization for all COVID-19 vaccines is a request to revoke the license of all approved COVID-19 vaccines, FDA denies Petitioner's request.

### C. Petitioner's Request that FDA Disallow Authorization of Any Newly Requested COVID-19 Vaccines

In the "Action Requested" section of the Petitions, Petitioner requests FDA to "Disallow Authorization for Any Newly Requested Covid 19 Authorizations."[120] Petitioner later states "Covid 19 vaccines should have never been developed or authorized for use."[121] We interpret this as a request for FDA to refrain from authorizing any future COVID-19 vaccines for emergency use and to refrain from approving any future COVID-19 vaccines under a BLA.

Petitioner has provided no evidence that would provide a basis for FDA to conclude that no future COVID-19 vaccine candidate could meet the EUA or BLA standards. Should FDA receive future requests for COVID-19 vaccine candidates, FDA would consider such requests on a case-by-case basis.[122] Accordingly, Petitioner's request for FDA to refrain from authorizing any future

[120] Petition at 1.
[121] *Id.* at 9.
[122] FDA has issued guidance describing factors the Agency intends to use in determining how to prioritize EUA requests for COVID-19 vaccine candidates. See October 2020 Guidance at 5 (citing EUA Guidance at 18-20).

COVID-19 vaccines for emergency use and to refrain from approving any future COVID-19 vaccines under a BLA is denied.

## IV. CONCLUSION

FDA has considered Petitioner's requests as they relate to authorized and approved COVID-19 vaccines. For the reasons given above, FDA denies the Petitions in their entirety.

Sincerely yours,

Peter Marks, MD, PhD
Director
Center for Biologics Evaluation and Research

cc: Dockets Management Staff