October 20, 2021

Aaron Siri
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New York, NY 10166

Re: Citizen Petition (Docket Number FDA-2021-P-1045)

Sent via email to: AARON@SIRILLP.COM

Dear Mr. Siri,

This letter responds to the citizen petition dated September 27, 2021 that you submitted to the Food and Drug Administration (FDA, the Agency, we) on behalf of the Informed Consent Action Network (ICAN) (Petitioner) relating to the Emergency Use Authorization (EUA) granted to ModernaTX, Inc. (Moderna), and the EUA granted to Janssen Biotech, Inc. (Janssen) for a vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (the CP).

In the CP, Petitioner requests that "the EUAs granted to [Moderna], and [Janssen] for their COVID-19 vaccines be revoked."[1]

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

Here is an outline of our response:

[1] CP at 2.

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.[2] On February 4, 2020, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (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 United States (U.S.) citizens living abroad, and that involves the virus that causes COVID-19.[3] 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.[4] In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.[5]

Commercial vaccine manufacturers and other entities are developing COVID-19 vaccine candidates, and clinical studies of these vaccines are underway and/or have been publicly reported. Between December 11, 2020 and February 27, 2021, FDA issued EUAs for three vaccines to prevent COVID-19, including vaccines sponsored by Pfizer Inc. (Pfizer),[6] Moderna, and Janssen. On August 23, 2021, the Agency approved the Biologics License Application (BLA) for Comirnaty (COVID-19 Vaccine, mRNA) to BioNTech Manufacturing GmbH.[7] Comirnaty is indicated for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older. The same day the Agency approved the BLA, the Agency also authorized the use of Comirnaty under the EUA for certain uses that are not included in the Comirnaty BLA as part of reissuing the letter of authorization for the Pfizer-BioNTech COVID-19 Vaccine.[8] On September 22, 2021 FDA reissued the EUA for the use of a single booster dose of Comirnaty or Pfizer-BioNTech COVID-19 Vaccine at least 6 months after completing the primary series of this vaccine in individuals: 65 years of age and older; 18 through 64 years of age at high risk of severe COVID-19; and 18 through 64 years of age whose

[2] 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.
[3] 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.
[4] 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.
[5] 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/.
[6] Hereinafter "Pfizer-BioNTech COVID-19 Vaccine".
[7] BioNTech Manufacturing GmbH is the biologics license holder for this vaccine, which is manufactured by Pfizer for BioNTech Manufacturing GmbH (hereinafter "BioNTech").
[8] *See, e.g.,* Pfizer-BioNTech Letter of Authorization, Sept. 22, 2021, at 2 n.9.

frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19.

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

A. Licensed Vaccines Are Safe, Pure, and Potent

FDA has a stringent regulatory process for licensing vaccines.[9,10] 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."[11] Prior to approval by FDA, vaccines are extensively tested in non-clinical studies and in humans. FDA's regulations describe some of the 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 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 a representative sample of the product and summaries of results of tests performed on the lot(s) represented by the sample.[12]

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 approved indication(s) and use. 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 has been demonstrated.[13] 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."[14] Therefore, the manufacturers of vaccines that have been licensed in the U.S. have necessarily demonstrated the safety of the vaccines within the meaning of the applicable statutory and regulatory provisions before the vaccines were licensed and allowed to be marketed.

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

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[9] 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.
[10] Vaccine Safety Questions and Answers, last updated March 2018, https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/vaccine-safety-questions-and-answers.
[11] Section 351(a)(2)(C)(i)(I) of the PHS Act.
[12] 21 CFR § 601.2(a).
[13] FDA, Vaccines, last updated January 2021, https://www.fda.gov/vaccines-blood-biologics/vaccines.
[14] 21 CFR § 601.2(d).

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 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 virus that causes COVID-19.[15] 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.[16]

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

[15] 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.
[16] 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.

trial. In the guidance document Emergency Use Authorization for Vaccines to Prevent COVID-19 (October 2020 Guidance), FDA has provided recommendations that describe key information that would support issuance of an EUA for a vaccine to prevent COVID-19.[17] In the October 2020 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.[18] 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.[19]

A Phase 3 trial of a vaccine is generally a large 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 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.[20] 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.

Investigational COVID-19 vaccines continue to be studied. Following clinical trials, manufacturers analyze data prior to submitting to FDA a BLA to request approval from FDA to market the vaccine. A BLA for a new vaccine includes information and data regarding the safety, effectiveness, chemistry, manufacturing and controls, and other details regarding the product. 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.

Importantly, FDA has made clear that any vaccine that meets FDA's standards for effectiveness is also expected to meet the Agency's safety standards. FDA has stated that the duration of safety follow-up for a vaccine authorized under an EUA may be shorter than with a BLA (which the Agency expects will ultimately be submitted by manufacturers of vaccines that are authorized under an EUA). Specifically, FDA's guidance to manufacturers recommends that data from Phase 3 studies to support an EUA include a median follow-up duration of at least 2

[17] Emergency Use Authorization for Vaccines to Prevent COVID-19; Guidance for Industry, October 2020, (October 2020 Guidance), https://www.fda.gov/media/142749/download.
[18] Id. at 3.
[19] Id. at 4.
[20] Development and Licensure of Vaccines to Prevent COVID-19; Guidance for Industry, June 2020, (June 2020 Guidance), https://www.fda.gov/media/139638/download.

months after completion of the full vaccination regimen.[21] Furthermore, robust safety monitoring will be conducted after a vaccine is made available. The monitoring systems include the Vaccine Adverse Event Reporting System (VAERS), FDA's Biologics Effectiveness and Safety (BEST) System, and the Centers for Disease Control and Prevention's (CDC) Vaccine Safety Datalink. In addition, FDA has a partnership with the Centers for Medicare & Medicaid Services (CMS) to study vaccine safety. Collectively, these programs will help detect any new, unusual and rare side effects after vaccination that might not have been observed during clinical trials, as well as monitor for increases in any known side effects.

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.

C. 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)] no longer exist;
- the criteria under [section 564(c)] 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.

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) is met and if certain circumstances exist.[22]

III. DISCUSSION

The CP pertains to the EUAs granted to Moderna and to Janssen. In the CP, Petitioner requests that "the EUAs granted to [Moderna], and [Janssen] for their COVID-19 vaccines be revoked."[23] The reason Petitioner puts forward: FDA has now approved Comirnaty.

[21] October 2020 Guidance at 10-11.
[22] Emergency Use Authorization of Medical Products and Related Authorities; Guidance for Industry and Other Stakeholders, January 2017, at 29, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities.
[23] CP at 2.

Specifically, Petitioner's argument as to why FDA should revoke the Moderna and Janssen EUAs is that "the requirements under federal law for continuing the EUA for Moderna and Janssen's COVID-19 vaccines are no longer satisfied" because Comirnaty "is an 'adequate, approved, and available alternative' vis-a-vis the other EUA COVID-19 vaccines."[24]

Petitioner asserts that "[i]f there is an 'adequate, approved, and available' COVID-19 vaccine, the conditions for permitting EUAs for other COVID-19 vaccines are no longer met,"[25] and that Comirnaty is an adequate, approved, and available alternative.

However, there is no basis for Petitioner's assertion that FDA must revoke the EUAs for the Moderna and Janssen COVID-19 vaccines, because there is no legal requirement to revoke the EUAs because of the approval of Comirnaty. The criteria for issuance of an EUA declare, in relevant part, that FDA may issue an EUA when "there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating" the disease or condition that is the subject of the public health emergency.[26]

First: Petitioner's argument ignores the discretion Congress provided to FDA in the statute. Nothing in the FD&C Act *requires* FDA to *revoke* existing EUAs simply because the conditions that gave rise to their issuance no longer apply. Indeed, the provision governing "Review and Revocation of Authorization" says that, if the criteria justifying the original issuance of an EUA "are no longer met," then FDA "*may* revise or revoke" that EUA.[27] The verb "may" is ordinarily permissive, particularly when the statute elsewhere uses the term "shall" to confer a mandatory Duty.[28] Further underscoring FDA's discretion, the EUA statute provides that all decisions regarding EUAs are "committed to agency discretion."[29]

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[24] CP at 3-4.
[25] CP at 2.
[26] Section 564(c)(3) of the FD&C Act.
[27] Section 564(g)(2) of the FD&C Act (emphasis added). In addition, section 564(g) of the FD&C Act also provides that if the circumstances in (b)(1) (i.e., a declaration that the circumstances exist justifying emergency use authorizations on the basis of a public health emergency) "no longer exist," then FDA also "may" revise or revoke an EUA. Notably, HHS's declaration of a public health emergency has not terminated. *See* 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 (issuing the COVID-19 EUA declaration, which remains in effect, that a public health emergency exists justifying the authorization of emergency use of drugs and biologics).
[28] S*ee Old Life Ins. Co. of Am. v. Garcia*, 411 F.3d 605, 614-15 (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, and 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." To the contrary, section 564 of the FD&C Act consistently uses "may" as permissive and "shall" as mandatory. *Compare, e.g.*, section 564(a) of the FD&C Act (providing that the Secretary "may" issue an EUA) *and id.* section 564(b)(1) of the FD&C Act (providing that the Secretary "may" declare a public emergency), *with, e.g., id.* section 564(b)(3) of the FD&C Act (providing that the Secretary "shall" provide notice in advance of terminating a declaration) *and id.* section 564(h)(1) of the FD&C Act (providing that the Secretary "shall" publish certain EUA actions in the Federal Register).
[29] *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 Procedures Act].").

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,"[30] because it allows the agency to permit continued distribution of EUA products and thereby removes the need for manufacturers to limit supply or delay seeking approval to exhaust supplies of authorized product.

Because Petitioner's understanding of the legal framework governing EUAs is flawed, the premise of the CP fails.

Second: Regarding the question of whether the approval of Comirnaty means that there is now adequate, available, approved COVID-19 vaccine at this time such that continuation of the EUAs is no longer justified, we note that petitioner has not provided any data or information supporting their view. In the view of FDA, one consideration in our assessment relates to availability, or demand and supply. There is still need and demand for COVID-19 vaccines and having sufficient supply is crucial for ensuring that vaccines are available to protect individuals against COVID-19. It is estimated that for the 18 years and older population for which the Moderna and Janssen COVID-19 vaccines are authorized, 22% have not received any dose of vaccine and only 67.6% are fully vaccinated.[31,32] This unvaccinated and partially vaccinated population represents

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[30] *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).

[31] CDC Covid Data Tracker Weekly Review, https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/ (last accessed Oct. 14, 2021).

[32] The Petition states that "the United States currently has a large surplus of Pfizer's COVID-19 vaccines," and that Pfizer is "ramping up production." The Petitioner's cites a STAT web article about surplus vaccine doses set to expire to support the contention that the U.S. has a surplus of Comirnaty and a Wall Street Journal article to support the contention that Pfizer is ramping up supplies. O. Goldhill, "States are sitting on millions of surplus Covid-19 vaccine doses as expiration dates approach", STAT (July 20, 2021), https://www.statnews.com/2021/07/20/states-are-sitting-on-millions-of-surplus-covid-19-vaccine-doses-as-expiration-dates-approach/ (last accessed Oct. 13, 2021). J. Hopkins, "Pfizer Lifts Covid-19 Vaccine Production Targets for 2021, 2022," Wall Street Journal (May 7, 2021), https://www.wsj.com/articles/pfizer-lifts-covid-19-vaccine-production-targets-for-2021-2022-11620425904#%E2%80%8C:%7E:%E2%80%8Ctext=Pfizer%20expects%20to%20produce%203,on%20social%2Dmedia%20site%20LinkedIn (last accessed Oct. 13, 2021). In addition to the web articles on the supply of Comirnaty, Petitioner cites "the CDC's data and Pfizer's public statements." Petitioner states that "there are currently over 32 million doses of Pfizer's vaccine sitting in United States vaccination centers, another over 53 million sitting in U.S. Government storage waiting to be distributed, and another 200 million doses that Pfizer will be delivering to the U.S. Government over the coming months." J. Hopkins, "Pfizer Lifts Covid-19 Vaccine Production Targets for 2021, 2022," Wall Street Journal (May 7, 2021), https://www.wsj.com/articles/pfizer-lifts-covid-19-vaccine-production-targets-for-2021-2022-11620425904#%E2%80%8C:%7E:%E2%80%8Ctext=Pfizer%20expects%20to%20produce%203,on%20social%2Dmedia%20site%20LinkedIn (last accessed Oct. 13, 2021). The sources cited by the Petitioner are not sufficient to establish that Comirnaty is an adequate, approved, and available alternative to the Moderna EUA and to the Janssen EUA product. The STAT website article is dated July 20, 2021 and discusses "doses likely expire this summer," but does not specify the availability of Comirnaty as of the date of the petition. The Wall Street Journal article Petitioner cites focuses on doses for distribution to developing countries and quotes the Chief Executive of Pfizer's statement that the increase in Pfizer's production projections are not solely for the United States, but that "[t]hese doses are not for the rich or poor, not for the north or south. These are doses for ALL." Even if the projected doses were all intended for the United States, the article focuses on Pfizer's projections for how many doses it would produce, rather than how have been produced since the article has been published. The CDC data that Petitioner cites also does not demonstrate that there is no adequate, approved, and available alternative. Although the CDC

need and demand for COVID-19 vaccines. Importantly, partially vaccinated individuals who received a first dose of the Moderna vaccine should receive a second dose of the same vaccine to complete the primary series; similarly, certain immunocompromised individuals who received two doses of Moderna, who are recommended to receive a third primary dose, should receive the same vaccine. Consequently, the approved vaccine cannot be expected to meet the demand for second and third primary series doses for those individuals. In addition to these individuals and the millions of individuals who remain unvaccinated, we anticipate further demand may come in the future for COVID-19 vaccines. For example, FDA has authorized the use of a single booster dose in certain circumstances. On the supply side, there is only one COVID-19 vaccine that is approved. In light of the need and demand for COVID-19 vaccines, there is not sufficient supply.

Another consideration is that Comirnaty may not be an adequate alternative. For example, some individuals may be allergic to some of the ingredients. Comirnaty is contraindicated for individuals with a known history of severe allergenic reaction to any component of the vaccine.[33] The CDC recommends that individuals who have had a severe allergic reaction or an immediate allergic reaction to any ingredient in an mRNA COVID-19 vaccine should not get either of the currently available mRNA COVID-19 vaccines.[34] To ensure that there are adequate vaccines available for individuals with a history of relevant allergic reactions, it is important for the public health that other vaccines remain authorized during the public health emergency. The Janssen vaccine uses an adenovirus vector, which may be an alternative to individuals for whom the mRNA-based Moderna and Pfizer-BioNTech/Comirnaty COVID-19 vaccines are contraindicated.

A further consideration is that there are also individuals for whom the two-dose regimen of Comirnaty may be unavailable; for example, if they have difficulty accessing healthcare providers (e.g., due to geographic or other circumstances such as mobility or housing insecurity challenges). For these individuals, the one-dose Janssen COVID-19 Vaccine may be important to ensure availability of a COVID-19 vaccine option. Finally, the storage conditions for Comirnaty may make the approved vaccine unavailable in some communities. Comirnaty undiluted vials are to be kept frozen until thawed, at which time they can only be kept in a

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COVID Data Tracker that Petitioner cites provides "U.S. COVID-19 Vaccine Delivered by Vaccine Type" and "U.S. COVID-19 Vaccine Administration by Vaccine Type," the website does not specify how much has been administered, how much vaccine has expired, or how much is available for administration at each location.

[33] *See* https://www.fda.gov/media/151707/download (Package Insert for Comirnaty listing contraindication, and stating that severe allergic reactions have been identified during postmarketing use of Comirnaty, including the Pfizer-BioNTech COVID-19 Vaccine under emergency use authorization). *See also* Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders, January 2017, at 8, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities (stating that a potential alternative product may be considered "inadequate" if, for example, there are contraindicating data for special circumstances or populations, such as individuals with a drug allergy).

[34] *See* CDC, COVID-19 Vaccines for People with Allergies, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/specific-groups/allergies.html. The CDC also recommends that if individuals are not able to get the second dose of an mRNA vaccine because they had an allergic reaction to the first dose, they should ask their doctor if they should get a different type of COVID-19 vaccine.

refrigerator for up to one month.[35] The Janssen COVID-19 Vaccine, by contrast, can be stored in a refrigerator.[36]

Separate and aside from the question of adequate, available, approved alternatives, it is important to recognize that there is always the possibility that a natural disaster or some other event could occur, and it is prudent to be prepared to try to minimize the impact such an event could have on the availability of COVID-19 vaccines. It is also important to recognize that the pandemic is still evolving and could do so in ways that might further impact the availability and demand for COVID-19 vaccines. For example, the emergence of viral variants could increase demand for the authorized and approved COVID-19 vaccines.

IV. CONCLUSION

FDA has considered Petitioner's requests to revoke the EUA granted to Moderna and the EUA granted to Janssen. For the reasons given in this letter, FDA denies the requests and therefore denies the CP in its entirety.

Sincerely,

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

cc: Dockets Management Staff

[35] *See* https://www.fda.gov/media/151707/download (Package Insert for Comirnaty describing storage instructions).
[36] *See* CDC, Janssen COVID-19 Vaccine (Johnson & Johnson) Storage and Handling Summary, https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/downloads/janssen-storage-handling-summary.pdf (describing storage conditions for the Janssen COVID-19 Vaccine).