November 15, 2022

Aaron Siri
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Re: Citizen Petitions (Docket Numbers FDA-2021-P-0337 and FDA-2022-P-1913)

Sent via email to: aaron@sirillp.com

Dear Mr. Siri,

This letter responds to two citizen petitions that you submitted to the Food and Drug Administration (FDA, the Agency, we) on behalf of the Informed Consent Action Network (Petitioner) (collectively, the Petitions). The first, dated March 24, 2021, relates to certain conditions of authorization of the Emergency Use Authorizations (EUAs) of three vaccines to prevent Coronavirus Disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (the March 2021 Petition). We sent an interim response to the March 2021 Petition on September 22, 2021. The second, received on August 12, 2022, requested removal of certain conditions of authorization of the EUAs of four vaccines to prevent COVID-19 (the August 2022 Petition).[1]

In the March 2021 Petition, Petitioner requests that FDA "take the actions listed below to assure enforcement of the conditions in the emergency use authorization ('EUA') for COVID-19 vaccines":

> 1. [p]rovide public notice to all state health departments, major health insurance carriers, major health systems, and other stakeholders that they are to comply with the following "conditions of authorization" in the EUAs and in 21 U.SC. § 360bbb-3(e), including that:
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> a. "All descriptive printed matter, advertising, and promotional material, relating to the use of the [] COVID-19 Vaccine[s] shall be consistent with the authorized labeling, as well as the terms set forth in [each] EUA, and meet the

[1] FDA has also received the petitions that you have submitted on behalf of ICAN regarding vaccines to prevent COVID-19 in the following dockets: FDA-2020-P-1601, FDA-2020-P-1768, FDA-2020-P-1769, FDA-2020-P-1770, FDA-2020-P-2096, FDA-2020-P-2180, FDA-2021-P-0529, FDA-2021-P-1045, FDA-2022-P-0872, and FDA-2022-P-1399. FDA has responded, or is responding, separately to those petitions.

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requirements set forth in section 502(a) and (n) of the FD&C Act and FDA implementing regulations;"

b. "All descriptive printed matter, advertising, and promotional material relating to the use of the []^{2} COVID-19 Vaccine clearly and conspicuously shall state that: This product has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 18 years of age and older; and The [sic] emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner;" and

c. "[I]ndividuals to whom the product is administered are informed of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks."

2. Ensure that each manufacturer of an FDA-authorized COVID-19 vaccine is complying with the requirement to "ensure that the terms of [its] EUA are made available to all relevant stakeholders," by requiring each to provide the FDA with a written list of the stakeholders to [sic] whom the manufacturer has notified of the terms of the EUA and provide a copy of the form of the notification sent by the manufacturer.

3. Ensure that emergency response stakeholders are complying with the FDA's requirement that "[e]mergency response stakeholders will ensure that vaccination providers within their jurisdictions are aware of [the EUA] letter of authorization, and the terms [t]herein," by notifying emergency response stakeholders of this obligation and requesting they each submit to the FDA notification of the steps taken to comply with this requirement.

March 2021 Petition at 2-3.

In the August 2022 Petition, Petitioner requests that FDA:

1. Remove the following EUA Advertising Condition in Moderna's COVID-19 vaccine EUA:

[2] Although the "Action Requested" section of the March 2021 Petition specifically uses the term "Janssen COVID-19 Vaccine" here, it is clear from the context of this petition that it is, in fact, also intended to apply to other COVID-19 vaccines authorized by FDA under EUA. We therefore have inserted brackets into this quotation from the March 2021 Petition.

All descriptive printed matter, advertising, and promotional material relating to the use of the Moderna COVID-19 Vaccine clearly and conspicuously shall state that:

This product has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 18 years of age and older, 12 through 17 years of age, 6 years through 11 years of age, or 6 months through 5 years of age as appropriate; and

The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

2. Remove the following EUA Advertising Condition in Pfizer-BioNTech's COVID-19 vaccine EUA:

   All descriptive printed matter, advertising, and promotional material relating to the use of the Pfizer-BioNTech COVID-19 Vaccine clearly and conspicuously shall state that:

   This product has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 12 years of age and older, in individuals 5 through 11 years of age, or in individuals 6 months through 4 years of age as appropriate; and

   The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

3. Remove the following EUA Advertising Condition in Janssen's COVID-19 vaccine EUA:

   All descriptive printed matter, advertising, and promotional material relating to the use of the Janssen COVID-19 Vaccine clearly and conspicuously shall state that:

   This product has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 18 years of age and older for whom other FDA-authorized or approved COVID-19 vaccines are not accessible or clinically

appropriate, and who elect to receive the Janssen COVID-19 Vaccine because they would otherwise not receive a COVID-19 vaccine; and

The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

4. Remove the following EUA Advertising Condition in Novavax's COVID-19 vaccine EUA:

   All descriptive printed matter, advertising, and promotional material relating to the use of the Novavax COVID-19 Vaccine clearly and conspicuously shall state that:

   This product has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 18 years of age and older; and

   The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

August 2022 Petition at 1-3.

In this letter, we discuss the emergency use authorization of vaccines to prevent COVID-19. We then turn to the requests contained in the Petitions. We consider each of your requests in light of the legal standards for FDA action, and provide our conclusions based on the facts and the law.

This letter responds to the Petitions in full. FDA has carefully reviewed the Petitions and other relevant 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 21 CFR § 10.30(e)(3), and for the reasons stated below, FDA is denying the Petitions.

Here is an outline of our response:

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 564 of the Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. § 360bbb-3), 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] While this declaration enables certain funding authorities, it is not relevant to the authority to issue or maintain EUAs.

Commercial vaccine manufacturers and other entities are developing COVID-19 vaccine candidates, and clinical studies of these vaccines are underway and/or have been completed. To date, FDA has issued EUAs for COVID-19 vaccines ("the Authorized COVID-19 Vaccines")

[3] Secretary of Health and Human Services 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.
[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/.

produced by four manufacturers. As described in the Scope of Authorization for the Authorized COVID-19 Vaccines, FDA issued the EUAs pursuant to section 564 of the FD&C Act.[7]

Since the original issuance of these EUAs, FDA has also approved two of the Authorized COVID-19 Vaccines. On August 23, 2021, FDA approved the first COVID-19 vaccine. FDA issued a biologics license for the Pfizer-BioNTech COVID-19 Vaccine, now marketed as Comirnaty, for the prevention of COVID-19 disease in individuals 16 years of age and older.[8] On January 31, 2022, the Agency approved a second COVID-19 vaccine. FDA issued a biologics license for the Moderna COVID-19 vaccine, now marketed as Spikevax, for the prevention of COVID-19 in individuals 18 years of age and older. FDA's EUAs remain in place. The EUAs cover certain uses of the approved vaccines that are not covered by the approvals as well as use of COVID-19 vaccines that are not the subject of approvals, as described in the letters of authorization.

A. Emergency Use Authorization

Congress established the Emergency Use Authorization (EUA) pathway to ensure that, during certain types of emergencies, potentially lifesaving uses of 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 justifying emergency use of vaccines, FDA may issue an EUA, which is different from the regulatory process for vaccine licensure.

Section 564 of the FD&C Act (21 U.S.C. § 360bbb-3) 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 or other threats specific to military forces when, among other criteria, there are no adequate, approved, and available alternatives.

As noted 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 United States (U.S.) citizens living abroad, and that involves the virus that causes COVID-19.[9] 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

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[7] For background regarding the EUAs for the vaccines produced by Pfizer, Inc.; ModernaTX, Inc.; Janssen Biotech, Inc.; and Novavax, Inc.; see https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines.

[8] Since then, FDA expanded the scope of the approval of Comirnaty to include use of the vaccine in individuals 12 through 15 years of age. *See* https://www.fda.gov/media/159727/download.

[9] 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.

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)).[10]

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 following statutory requirements are met:

- The agent referred to in the March 27, 2020 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 Biologics License Applications (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* (March 2022 Guidance), FDA has provided recommendations that describe key information that would support issuance of an EUA for a vaccine to prevent COVID-19.[11] In the March 2022 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.[12] 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.[13]

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[10] 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.

[11] Emergency Use Authorization for Vaccines to Prevent COVID-19; Guidance for Industry, March 2022 (March 2022 Guidance), https://www.fda.gov/media/142749/download. This guidance supersedes the guidance of the same title issued on May 25, 2021.

[12] Id. at 4.

[13] Id. at 4.

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.[14] 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 in Phase 2 or Phase 3 trials. 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 months after completion of the full vaccination regimen.[15] Furthermore, robust safety monitoring is 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.

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[14] Development and Licensure of Vaccines to Prevent COVID-19; Guidance for Industry, June 2020, https://www.fda.gov/media/139638/download.

[15] March 2022 Guidance at 11.

An EUA is granted through a letter authorizing the emergency use(s) of the product that is signed by the Commissioner (or designee) and includes a description of the authorized product and its use(s), any contraindications for the product, the criteria for issuance of the authorization, the scope of the authorization, waiver of certain requirements (if applicable), and any conditions on the authorized use (letter of authorization, or LOA).[16] As explained in the EUA guidance, section 564(e)(1)(A) directs FDA to establish certain conditions for the emergency use of unapproved products, as described in the statute. In addition, FDA may, under section 564(e)(1)(B) of the FD&C Act, on a case-by-case basis and to the extent feasible given the circumstances of a particular public health emergency, establish certain discretionary conditions that FDA finds to be necessary or appropriate to protect the public health.[17] An authorized EUA consists of (1) the signed LOA and (2) any accompanying authorized materials (e.g., Fact Sheet for health care professionals, Fact Sheet for recipients, instructions for use, etc.).[18] EUA letters of authorization and accompanying authorized materials are made publicly available via FDA's COVID-19 Vaccines or EUA webpages.[19]

II. DISCUSSION

A. The March 2021 Petition

1. Requests for Enforcement Actions

Petitioner requests that FDA take the specific actions requested "to assure enforcement of the conditions in the [EUA] for COVID-19 vaccines." March 2021 Petition at 1.

It thus appears that Petitioner is requesting that the Agency initiate enforcement action or a related regulatory activity. Decisions with respect to such matters are within the discretion of the Agency and are generally made on a case-by-case basis. They are not within the scope of FDA's citizen petition procedures. Under § 10.30(k), citizen petitions may not be used for "the referral of a matter to a United States attorney for the initiation of court enforcement action and related correspondence." By its terms, § 10.30(k) excludes from the Agency's citizen petition procedures not only requests for referrals to a U.S. Attorney but also "related correspondence." Because the Department of Justice represents FDA in actions brought to enforce the FD&C Act and other statutes that we administer and because FDA typically refers such cases to the United States Department of Justice through the local United States Attorney's Office, Agency decisions to take enforcement actions are decisions related to (and involve correspondence related to) the referral of a matter to a U.S. Attorney for the initiation of a court enforcement action for

[16] Emergency Use Authorization of Medical Products and Related Authorities; Guidance for Industry and Other Stakeholders, January 2017 (EUA Guidance), at 21, https://www.fda.gov/media/97321/download.
[17] Emergency Use Authorization of Medical Products and Related Authorities; Guidance for Industry and Other Stakeholders, January 2017 (EUA Guidance), at 26, https://www.fda.gov/media/97321/download.
[18] Emergency Use Authorization of Medical Products and Related Authorities; Guidance for Industry and Other Stakeholders, January 2017 (EUA Guidance), at 21, https://www.fda.gov/media/97321/download.
[19] Emergency Use Authorization, FDA, at https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines or https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#vaccines.

violations of the FD&C Act.[20] Additionally, under 21 CFR 10.30, the scope of FDA's citizen petition procedures is described as authorizing a person to petition the Agency to issue, amend, or revoke a regulation or order or to take or refrain from taking any other form of "administrative action." FDA regulations at 21 CFR 10.3 define "administrative action" to include "every act, including the refusal or failure to act, involved in the administration of any law by the Commissioner, except that it does not include the referral of apparent violations to U.S. attorneys for the institution of civil or criminal proceedings or an act in preparation of a referral." Agency decisions to take enforcement action are decisions related to the "referral of apparent violations to U.S. attorneys for the institution of civil or criminal proceedings, or acts in preparation of such referrals."

Therefore, insofar as the March 2021 Petition is premised on a request that FDA take judicial enforcement action against any person, we deny the petition as being outside the scope of the citizen petition process. Such denial is consistent with the Agency's regulations and longstanding practice with respect to petitions that ask FDA to take enforcement action, because such requests are not the proper subject of citizen petitions.[21] The Agency makes decisions regarding whether to pursue enforcement actions on a case-by-case basis, considering all relevant facts and circumstances. Where appropriate, the Agency considers information provided by individuals or entities involved, as well as other information regarding the specific

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[20] *See* Administrative Practices and Procedures, Notice of Proposed Rulemaking, 40 FR 40682, 40683 (Sept. 3, 1975) (preamble to proposed rule establishing FDA's citizen petition procedural regulations, stating that "any activity in preparation or incidental" to the referral of apparent violations to United States attorneys "is specifically excluded" from citizen petition procedures and that "matters related to the agency's law enforcement role are not included" in the definition of "administrative action" under the citizen petition procedural regulations).

[21] *See, e.g.,* Letter from Peter Marks, Director for Center for Biologics Evaluation and Research, U.S. Food and Drug Administration, to George M. Stone, Jr., Patients for Access to Advanced Therapy for Hemophilia (Sept. 25, 2020) (response letter denying citizen petition request for the Agency to take enforcement action because such requests are excluded from the citizen petition procedures), *available at* *https://www.regulations.gov/document/FDA-2019-P-6099-0005;* Letter from Rebecca Buckner, Acting Deputy Director for Regulatory Affairs, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, to Gary Ruskin, Executive Director, U.S. Right to Know (Oct. 26, 2017) (response letter denying citizen petition and citing 21 CFR 10.30(k) for the proposition that requests for FDA to initiate enforcement action are not the proper subjects of a citizen petition), *available at* *https://www.regulations.gov/document/FDA-2015-P-1187-0004;* Letter from Janet Woodcock, Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration to Alexandra Haner, Haner & Kuo, PLLC (Sept. 23, 2016) (response letter denying citizen petition and citing 21 CFR 10.30(k) for the proposition that requests for the Agency to initiative enforcement actions are not within the scope of FDA's citizen petition procedures), *available at* *https://www.regulations.gov/document/FDA-2016-P-1249-0004;* Letter from Janet Woodcock, Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration to Nancy Cariker-Moon, Alcon Research, Ltd. (July 27, 2012) (response letter denying citizen petition and stating that requests for the Agency to initiate enforcement actions are not within the scope of FDA's citizen petition procedures), *available at* *https://www.regulations.gov/document/FDA-2012-P-0431-0003;* Letter from Margaret O'K Glavin, Associate Commissioner for Regulatory Affairs, U.S. Food and Drug Administration, to Wiley Rein & Fielding LLP (Jan. 9, 2008) (response to citizen petition denying certain requested actions on the basis that requests for enforcement action are not within the scope of FDA's citizen petition procedures), *available at* *https://www.regulations.gov/document/FDA-2005-P-0517-0649;* Letter from Margaret O'K Glavin, Associate Commissioner for Regulatory Affairs, U.S. Food and Drug Administration, to Jane Houlihan and Arianne Callender, Environmental Working Group (Sept. 29, 2005) (response letter denying citizen petition requests for the Agency to take certain enforcement actions), *available at* https://www.regulations.gov/document/FDA-2004-P-0018-0005. There are numerous other examples in which FDA has denied citizen petition requests for the Agency to take enforcement action because such requests are not the proper subject of citizen petitions.

circumstances of the matter.[22] At this time, we are not taking the actions you requested. However, if FDA becomes aware of any individuals or organizations violating requirements to which they are subject relating to the COVID-19 Vaccine EUAs, FDA is able to consider taking action as appropriate.

Insofar as Petitioner is requesting that FDA take actions other than initiating enforcement actions, we discuss those requests below and deny the requests for the independent reasons described below.

2. Petitioner's Requests That FDA Provide Public Notice to Stakeholders That They Are to Comply with Certain Conditions of Authorization in the EUA Letters of Authorization and in 21 U.S.C. § 360bbb-3(e)

Petitioner requests that FDA

> 1. [p]rovide public notice to all state health departments, major health insurance carriers, major health systems, and other stakeholders that they are to comply with the following "conditions of authorization" in the EUAs and in 21 U.S.C. § 360bbb-3(e), including that:
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> a. "All descriptive printed matter, advertising, and promotional material, relating to the use of the [] COVID-19 Vaccine[s] shall be consistent with the authorized labeling, as well as the terms set forth in [each] EUA, and meet the requirements set forth in section 502(a) and (n) of the FD&C Act and FDA implementing regulations;"
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> b. "All descriptive printed matter, advertising, and promotional material relating to the use of the [][23] COVID-19 Vaccine clearly and conspicuously shall state that: This product has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 18 years of age and older; and The [sic] emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner;" and
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> c. "[I]ndividuals to whom the product is administered are informed of the significant known and potential benefits and risks of such use, and of the

[22] *See e.g.*, *Heckler v. Chaney*, 470 U.S. 821, 831 (1985) ("[A]n agency decision not to enforce often involves a complicated balancing of a number of factors which are peculiarly within its expertise.").

[23] Although the "Action Requested" section of the March 2021 Petition specifically uses the term "Janssen COVID-19 Vaccine" here, it is clear from the context of the March 2021 Petition that the March 2021 Petition in fact applies to other COVID-19 vaccines authorized by FDA under EUA as well. We therefore have inserted brackets into this quotation from the March 2021 Petition.

extent to which such benefits and risks are unknown; and of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks."

March 2021 Petition at 2.

In this letter, for purposes of brevity, we quote language from the Janssen COVID-19 Vaccine EUA documentation (LOAs and Fact Sheets); however, the other Authorized COVID-19 Vaccines' EUA documentation is, in relevant part, substantially similar, and the reasoning in this letter applies with regard to all the COVID-19 vaccines under EUA.

We note that, for all COVID-19 vaccines authorized at the time the March 2021 Petition was submitted (March 24, 2021), the EUA LOAs and Fact Sheets in place on that date have since been reissued to include certain revisions.[24] The provisions of the EUA LOAs and Fact Sheets that were in place on March 24, 2021 that are referenced in this letter are consistent with those in the more recently issued EUA LOAs and Fact Sheets, as indicated below.

a. FDA's Public Outreach Regarding Emergency Use Authorization of Vaccines to Prevent COVID-19

For each EUA for a vaccine to prevent COVID-19, FDA has engaged in extensive public outreach. Examples of these outreach activities have included: Press releases (available in two languages) about the issuance of the EUAs; posting on FDA's website of the Letters of Authorization (LOAs), Fact Sheets for Healthcare Providers Administering Vaccine (Vaccination Providers), Fact Sheets for Recipients and Caregivers (available in six languages), FDA's Decision Memoranda summarizing FDA's review of the authorization requests, and Frequently Asked Questions relating to the authorization and vaccine; social media outreach; targeted outreach to stakeholder groups such as medical professional organizations, consumer groups, patient advocacy groups, and industry; Dear International Colleague Letters; media advisories; media calls, press conferences, and interviews, including those livestreamed on YouTube, with the Commissioner and other FDA officials; 50-state teleconferences with governors, their federal representatives, and state health officials, as well as state, local, and tribal associations; targeted outreach by FDA's Office of Minority Health and Health Equity to their stakeholders; outreach to nearly 5,600 stakeholder groups, including local media, state and local health departments, consumers and civic groups, community and public health partners, and academia; and Federal Register Notices providing notification of, and information about, the EUAs. In addition, FDA has made available links to the EUA Letters of Authorization, which include the conditions of authorization and the basis for the authorization. Thus, for all EUAs

[24] Links to the latest version of all documentation relating to the COVID-19 vaccines authorized for emergency use (as well as documentation for those FDA has approved) can be found on FDA's COVID-19 Vaccines or EUA webpages at https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines or https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#vaccines.

for vaccines to prevent COVID-19, our outreach has included providing "public notice" of the EUA through multiple channels. FDA's extensive outreach efforts have resulted in making available comprehensive EUA information to relevant stakeholders, including information about the conditions of authorization.

b. Petitioner's Requests Relating to Public Notice

As explained above, FDA may establish conditions on an EUA.[25] Section 564(e)(1)(A) provides for FDA to establish certain conditions for the emergency use of unapproved products, as described in the statute.[26] For example, under section 564(e)(1)(A)(ii), FDA is to establish "[a]ppropriate conditions designed to ensure that individuals to whom the product is administered are informed," (I) that the Secretary "has authorized the emergency use of the product," (II) of "the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown," and (III) of "the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks." Under section 564(e)(1)(B) of the FD&C Act, on a case-by-case basis and to the extent feasible given the circumstances of a particular public health emergency, FDA may establish certain discretionary conditions on an EUA that FDA finds to be necessary or appropriate to protect the public health.[27] Under section 564(e)(4) of the FD&C Act, one discretionary condition that FDA may place is a condition on "advertisements and other promotional descriptive printed matter (e.g., press releases issued by the EUA sponsor) relating to the use of an EUA product, such as requirements applicable to prescription drugs under section 502(n)."[28] Consistent with section 564, FDA has established conditions of authorization for each of the COVID-19 vaccines under EUA. Indeed, the conditions of the EUAs for which the March 2021 Petition requests FDA provide "public notice" are consistent with the statute. Specifically, the LOAs require that vaccine recipients be provided with authorized labeling, which includes a fact sheet informing vaccine recipients of information that is consistent with section 564(e)(1)(A) (i.e., information about the significant known and potential benefits and risks of the vaccines, the extent to which the risks are unknown, the option to accept or refuse, and available alternatives). In addition, the conditions related to printed matter and promotional material are consistent with section 564(e)(4), in that the conditions establish requirements for advertisements and other promotional descriptive matter relating to the use of an EUA product. All of FDA's conditions of authorization are laid out in the LOA for each of the authorized COVID-19 vaccines.[29]

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[25] Emergency Use Authorization of Medical Products and Related Authorities, Guidance for Industry and Other Stakeholders, January 2017, at 26-27.

[26] In accordance with section 564(e)(2)(A), FDA's authority to establish conditions of emergency use authorization also applies to unapproved uses of approved products.

[27] *Emergency Use Authorization of Medical Products and Related Authorities* Emergency Use Authorization of Medical Products and Related Authorities; Guidance for Industry and Other Stakeholders, January 2017 (EUA Guidance) at 26, https://www.fda.gov/media/97321/download.

[28] *Emergency Use Authorization of Medical Products and Related Authorities* Emergency Use Authorization of Medical Products and Related Authorities; Guidance for Industry and Other Stakeholders, January 2017 (EUA Guidance) at 27, https://www.fda.gov/media/97321/download.

[29] FDA Letter of Authorization for the Emergency Use Authorization for Janssen COVID-19 Vaccine (reissued May 5, 2022), available at https://www.fda.gov/media/146303/download (May 2022 Janssen LoA); FDA Letter of

The language included in quotation marks in subsections (1)(a) and (b) of Petitioner's requests appears to be based on the following language in the Conditions of Authorization section, which was included in all of the Letters of Authorization for COVID-19 vaccines at the time the March 2021 Petition was submitted, and which continues to be included in the EUAs. For ease of reading, we excerpt the language from the Letter of Authorization for the Janssen COVID-19 Vaccine in effect at the time the March 2021 Petition was submitted:

> Conditions Related to Printed Matter, Advertising and Promotion
>
> X. All descriptive printed matter, advertising, and promotional material, relating to the use of the Janssen COVID-19 Vaccine shall be consistent with the authorized labeling, as well as the terms set forth in this EUA, and meet the requirements set forth in section 502(a) and (n) of the FD&C Act and FDA implementing regulations.
>
> Y. All descriptive printed matter, advertising, and promotional material relating to the use of the Janssen COVID-19 Vaccine clearly and conspicuously shall state that:
>
> - This product has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 18 years of age and older; and
>
> - The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

FDA Letter of Authorization for the Emergency Use Authorization for the Janssen COVID-19 Vaccine, February 27, 2021 (February 2021 Janssen LOA) at 9.[30]

Authorization for the Emergency Use Authorization for Pfizer-BioNTech COVID-19 Vaccine (reissued Oct. 12, 2022), available at https://www.fda.gov/media/150386/download; FDA Letter of Authorization for the Emergency Use Authorization for Moderna COVID-19 Vaccine (reissued Oct. 12, 2022), available at https://www.fda.gov/media/144636/download; FDA Letter of Authorization for the Emergency Use Authorization for Novavax COVID-19 Vaccine, Adjuvanted (reissued Oct. 19, 2022), available at https://www.fda.gov/media/159902/download.

[30] The Janssen EUA LoA reissued May 5, 2022 includes additional language in the first bullet in paragraph Y: "This product has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 18 years of age and older for whom other FDA-authorized or approved COVID-19 vaccines are not accessible or clinically appropriate, and who elect to receive the Janssen COVID-19 Vaccine because they would otherwise not receive a COVID-19 vaccine; and…" (emphasis added). FDA Letter of Authorization for the

By placing the LOAs on our website, FDA has made the LOAs publicly available. FDA has therefore already provided "public notice" of the excerpted conditions, because the publicly available LOAs set forth the excerpted conditions. This broad "public notice" includes notice to "all state health departments, major health insurance carriers, major health systems, and other stakeholders." In other words, this "public notice" includes notice to the very stakeholders to whom the March 2021 Petition asks we provide "public notice." In addition, as described above, our various outreach activities have also resulted in "public notice."

With this background in mind, we turn to the March 2021 Petition's statement of grounds.

Petitioner references the LOAs for the EUAs, stating that they

> make the same finding for each of the three COVID-19 Vaccines: "it is reasonable to believe that the [] COVID-19 Vaccine may be effective. Additionally, it is reasonable to conclude, based on the totality of the scientific evidence available, that the known and potential benefits of the [] COVID-19 Vaccine outweigh its known and potential risks."[] Therefore, for [sic] any unequivocal statement by any manufacturer, stakeholder, or vaccination provider that these vaccines are proven "safe and effective" is not consistent with the terms of the EUA and should not be permitted.

March 2021 Petition at 7 (footnote omitted; emphasis omitted).[31]

Petitioner asserts that entities are making statements that are not "consistent with the terms set forth in each EUA." March 2021 Petition at 7.

Petitioner asserts that

Janssen COVID-19 Vaccine (reissued May 5, 2022) (May 2022 Janssen LOA) at 11, https://www.fda.gov/media/146303/download.

[31] Petitioner's footnote links to three FDA Briefing Documents, but Petitioner appears to be quoting from the LOAs in place on the date the March 2021 Petition was submitted. For example, the February 27, 2021 Janssen LOA states "[b]ased on these data, and review of manufacturing information regarding product quality and consistency, it is reasonable to believe that the Janssen COVID-19 Vaccine may be effective. Additionally, it is reasonable to conclude, based on the totality of the scientific evidence available, that the known and potential benefits of the Janssen COVID-19 Vaccine outweigh its known and potential risks, for the prevention of COVID-19 in individuals 18 years of age and older" (emphasis added). February 27, 2021 Janssen LOA at 2. The Janssen LoA reissued on May 5, 2022 contains similar language: "Based on these data, and review of manufacturing information regarding product quality and consistency, FDA concluded it was reasonable to believe that the Janssen COVID-19 Vaccine may be effective. Additionally, FDA concluded, based on the totality of the scientific evidence available, that the known and potential benefits of the Janssen COVID-19 Vaccine outweigh its known and potential risks, for the prevention of COVID-19 in individuals 18 years of age and older" (emphasis added). May 2022 Janssen LOA at 2, available at https://www.fda.gov/media/146303/download. The LOAs for Moderna COVID-19 Vaccine and Pfizer-BioNTech COVID-19 Vaccine in place when the March 2021 Petition was submitted, as well as the LOAs for those vaccines reissued in 2022, contain similar language. See February 25, 2021 LOA for Moderna COVID-19 Vaccine at 2; Oct. 12, 2022 LOA for Moderna COVID-19 Vaccine at 5; February 25, 2021 LOA for Pfizer-BioNTech COVID-19 Vaccine at 2; Oct. 12, 2022 LOA for Pfizer-BioNTech COVID-19 Vaccine at 5.

> [t]he Centers for Disease Control and Prevention, for example, claims that "COVID-19 vaccines are safe and effective."[]

March 2021 Petition at 8 (footnote omitted). Petitioner further asserts that "[n]umerous public health agencies are mimicking the CDC's unsupported claim despite the inconsistency with the FDA's EUAs and are stating that these vaccines are proven safe and effective." March 2021 Petition at 8.

Petitioner asserts that "[t]he following FDA requirements in the EUAs is [sic] simply not being followed or enforced: 'All descriptive printed matter, advertising, and promotional material relating to the use of the COVID-19 Vaccines clearly and conspicuously shall state that: This product has not been approved or licensed by FDA.'" March 2021 Petition at 4. In particular, Petitioner asserts that

> [t]here are hundreds, if not thousands, of social media posts regarding COVID-19 Vaccines being publicly shared by health agencies in almost every state across the country. There are also emails, newsletters, mailings, and other communications being distributed to promote the vaccines. These messages are all promoting the COVID-19 Vaccines to the public and are not including the required disclosure that these vaccines are not approved or licensed by the FDA.

March 2021 Petition at 4. Petitioner provides two examples of state health departments that Petitioner claims were not complying with relevant law regarding promotional material relating to the use of the Authorized COVID-19 Vaccines.

Petitioner's first example refers to the website of the New York State Department of Health (NYS DOH). Petitioner asserts that, as of January 26, 2021, this website "provide[d] materials to encourage and 'educate' people about the COVID-19 Vaccines" and included "social media materials…meant to be shared by New Yorkers to help spread the word." March 2021 Petition at 4. Petitioner asserts that that website included a poster containing the statements "[t]he COVID-19 vaccine is safe and effective" and "[t]he COVID-19 vaccine went through the same rigorous approval process that all vaccines go through." March 2021 Petition at 4. Petitioner further asserts that the website provided a "'Sample Message' for individuals to use on social media" which read, in part, "'The vaccine is safe and effective. It was approved by the FDA, the CDC, and NY's independent vaccine panel'" (emphasis omitted). March 2021 Petition at 5. Petitioner asserts that "[t]his social media messaging…made the false claim that the FDA 'approved' a COVID-19 vaccine. This is categorically false." March 2021 Petition at 5. Petitioner states that Petitioner contacted NYS DOH and that NYS DOH has since removed this graphic and language from its website. March 2021 Petition at 5.

Petitioner's second example refers to a Facebook posting by the Michigan Department of Health and Human Services (MDHHS). Petitioner asserts that, as of March 8, 2021, this posting read, in part, "[o]n the journey to FDA approval, each COVID-19 vaccine had to pass through the same thresholds of research & testing as every other vaccine. And it's important to know that all three of the approved COVID-19 vaccines were proven to be safe and 100% effective in preventing hospitalization and death in the clinical trials" and "[a]ll 3 vaccines are proven to be

safe and effective." March 2021 Petition at 6. Petitioner asserts that this messaging "claims that the FDA 'approved' a COVID-19 vaccine. This is categorically false." March 2021 Petition at 6. Petitioner also states that "the three COVID-19 Vaccines are still undergoing clinical trials, hence they were also spreading misinformation when they claimed that these EUA authorized products 'had to pass through the same thresholds of research & testing as every other vaccine[]'" (emphasis omitted). March 2021 Petition at 6. Petitioner references the Fact Sheets for Recipients for the vaccines that "state that the vaccines 'ha[ve] not undergone the same type of review as an FDA-approved or cleared product.'" March 2021 Petition at 6. Petitioner states that Petitioner contacted MDHHS and that MDHHS has since removed references to "approved" vaccines. March 2021 Petition at 6.

In reviewing the March 2021 Petition's request with respect to printed matter and promotional material, we evaluate whether the March 2021 Petition has supported its request that FDA provide "public notice" regarding the conditions in the Letters of Authorization related to print matter and promotional material. As explained above, insofar as Petitioner is requesting that the Agency initiate enforcement action or a related regulatory activity in response to statements made by public health agencies, such requests are not within the scope of FDA's citizen petition procedures. Insofar as Petitioner is asserting that FDA needs to remedy a supposed deficiency by providing "public notice" regarding the conditions related to printed matter and promotional material, the March 2021 Petition does not identify any legal requirement for this. FDA's EUAs are consistent with the provisions in section 564(e) of the FD&C Act regarding conditions on "advertisements and other promotional descriptive printed matter that relate to the emergency use of a product" that FDA has discretion to establish. Nothing in the FD&C Act or relevant regulations requires FDA to take additional "public notice" actions regarding the conditions, and Petitioner has not demonstrated that FDA's actions are inconsistent in any way with the requirements of the FD&C Act or the regulations. Thus, the March 2021 Petition has not demonstrated that FDA must provide additional "public notice" of the EUA conditions related to printed matter and promotional material. In addition, as we explained above, we have already provided ample "public notice."

The March 2021 Petition's request that FDA provide "public notice" also includes a request that FDA provide "public notice" to stakeholders about information that is required to be made available directly to vaccine recipients. Specifically, the March 2021 Petition requests that FDA provide public notice that:

> "[I]ndividuals to whom the product is administered are informed of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks."

March 2021 Petition at 2.

This request relates to the EUA statute's provision that the Secretary may impose "[a]ppropriate conditions designed to ensure that individuals to whom the product is administered are

informed" (i) that the Secretary "has authorized the emergency use of the product," (ii) of "the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown," and (iii) of "the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks." Section 564(e)(1)(A)(ii). For the COVID-19 vaccines authorized under an emergency use authorization, FDA has imposed these informational conditions by requiring the distribution to potential vaccine recipients of authorized labeling in the form of a Fact Sheet with implementing language. For example, the Fact Sheet for Recipients and Caregivers for Janssen COVID-19 Vaccine describes the emergency use authorization, describes the vaccine's risks and benefits, provides information about available alternatives, and states: "Under the EUA, there is an option to accept or refuse receiving the vaccine. Should you decide not to receive the Janssen COVID-19 Vaccine, it will not change your standard medical care."[32,33] These Fact Sheets are required to be distributed to vaccine recipients under the EUA, and they are also publicly available for viewing on FDA's website. Petitioner has not provided evidence, and FDA has no other information suggesting, that vaccine recipients or their caregivers have not had access to the fact sheets for recipients. In addition, the March 2021 Petition does not explain any legal requirement for FDA to provide additional "public notice" of these informational conditions.

For the reasons described above, FDA denies Petitioner's request to further "[p]rovide public notice" regarding the conditions of authorization in the EUAs for the Authorized COVID-19 Vaccines.

3. Petitioner's Requests Relating to Actions Taken by COVID-19 Vaccine Manufacturers

Petitioner requests that FDA

> [e]nsure that each manufacturer of an FDA-authorized COVID-19 vaccine is complying with the requirement to "ensure that the terms of [its] EUA are made available to all relevant stakeholders," by requiring each to provide the FDA with a written list of the stakeholders to whom the manufacturer has notified of the

[32] Fact Sheet for Recipients and Caregivers, Emergency Use Authorization (EUA) of the Janssen COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) (May 5, 2022), at 6, available at https://www.fda.gov/media/146305/download.

[33] The March 2021 Petition asserts that "[t]here are federal, state, and private employers across the country mandating that their employees receive COVID-19 vaccines which are unapproved and unlicensed. These mandates fly in the face of 21 U.S.C. § 360bbb-3 and the FDA's EUAs, including the Healthcare Provider and Recipient Fact Sheets, which make clear an individual's statutory right to refuse the product." March 2021 Petition at 8. Regarding mandates and the option to accept or refuse vaccination, we refer you to the Memorandum Opinion for the Deputy Counsel to the President available on the United States Department of Justice website at https://www.justice.gov/sites/default/files/opinions/attachments/2021/07/26/2021-07-06-mand-vax.pdf. To the extent the March 2021 Petition asserts that the EUAs address whether third parties may require employees to receive vaccines, we note that the EUAs do not address such mandates.

> terms of the EUA and provide a copy of the form of the notification sent by the manufacturer.

March 2021 Petition at 2.

The quoted language in this request appears to be taken from the EUA LOAs. For example, the February 2021 Janssen LoA provides that

> Janssen Biotech, Inc. will ensure that the terms of this EUA are made available to all relevant stakeholders (e.g., emergency response stakeholders, authorized distributors, and vaccination providers) involved in distributing or receiving the authorized Janssen COVID-19 Vaccine. Janssen Biotech, Inc. will provide to all relevant stakeholders a copy of this letter of authorization and communicate any subsequent amendments that might be made to this letter of authorization and its authorized labeling.

February 2021 Janssen LoA at 5 (emphasis added).[34]

Petitioner has provided no evidence, and FDA has no other information suggesting, that any holders of EUAs for vaccines to prevent COVID-19 are failing to ensure that the terms of the EUAs are made available to relevant stakeholders. Because the March 2021 Petition does not provide evidence that EUA holders are failing to comply with this condition of authorization, the March 2021 Petition has not provided a justification for why FDA should require manufacturers to provide FDA with a list of stakeholders notified or to provide FDA with a copy of the form of the notification. Furthermore, the March 2021 Petition has not identified any legal basis for requiring this. For these reasons, FDA denies these requests.

4. Petitioner's Requests Relating to Actions Taken by Emergency Response Stakeholders

Petitioner requests that FDA

> [e]nsure that emergency response stakeholders are complying with the FDA's requirement that "[e]mergency response stakeholders will ensure that vaccination providers within their jurisdictions are aware of [the EUA] letter of authorization, and the terms [t]herein," by notifying emergency response stakeholders of this obligation and requesting they each submit to the FDA notification of the steps taken to comply with this requirement.

March 2021 Petition at 2-3.

The quoted language in this request appears to be taken from the EUA LOAs. For example, the February 2021 Janssen LOA provides that

[34] The May 2022 Janssen LoA also contains this language at 8.

> [e]mergency response stakeholders will ensure that vaccination providers within their jurisdictions are aware of this letter of authorization, and the terms herein and any subsequent amendments that might be made to the letter of authorization, instruct them about the means through which they are to obtain and administer the vaccine under the EUA, and ensure that the authorized labeling [i.e., Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Fact Sheet for Recipients and Caregivers] is made available to vaccination providers through appropriate means (e.g., e-mail, website).

February 2021 Janssen EUA LOA, at 7 (emphasis added).[35]

Petitioner has provided no evidence that any emergency response stakeholders are failing to "[e]nsure that vaccination providers within their jurisdictions are aware of [the EUA] letter of authorization, and the terms [t]herein." In addition, as described above, FDA has already engaged in extensive public outreach to stakeholders about the EUAs for vaccines to prevent COVID-19. For these reasons, FDA does not consider it necessary to further "notify[] emergency response stakeholders of this obligation" or require submissions to FDA regarding this. For these reasons, we deny these requests.

B. The August 2022 Petition

1. Petitioner's Requests to Remove the Advertising Condition from the COVID-19 Vaccine EUA Letters of Authorization

In the August 2022 Petition, Petitioner requests the removal of the "Advertising Condition" in the EUAs for the Moderna COVID-19 Vaccine, the Pfizer-BioNTech COVID-19 Vaccine, the Janssen COVID-19 Vaccine, and the Novavax COVID-19 Vaccine, Adjuvanted. Petitioner's first request reads

> Remove the following EUA Advertising Condition in Moderna's COVID-19 vaccine EUA:
>
> > All descriptive printed matter, advertising, and promotional material relating to the use of the Moderna COVID-19 Vaccine clearly and conspicuously shall state that:
> >
> > This product has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 18 years of age and older, 12 through 17 years of age, 6 years through 11 years of age, or 6 months through 5 years of age as appropriate; and

[35] The May 2022 Janssen LoA also contains this language at 10.

> The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

August 2022 Petition at 3. For purposes of brevity in this letter, we will not reproduce Petitioner's other three requests here; they differ from this request involving Moderna COVID-19 Vaccine only in the name of the authorized COVID-19 vaccine and the description of the indications for which use of that vaccine is authorized.

The letters of authorization for all four of the Authorized COVID-19 Vaccines include a section entitled "Conditions Related to Printed Matter, Advertising, and Promotion" containing a requirement that the statements referenced by Petitioner appear in such communications.

Petitioner states that "it is apparent that not all stakeholders, including public health agencies on both the federal and state levels, and vaccination providers, are abiding by the EUA Advertising Conditions." August 2022 Petition at 5. Petitioner asserts that

> [t]here are hundreds, if not thousands, of social media posts regarding COVID-19 Vaccines being publicly shared by health agencies in almost every state across the country, as well as emails, newsletters, mailings, and other communications by health agencies, promoting COVID-19 vaccines to the public that do not include the required language that these vaccines are not approved or licensed by the FDA.

August 2022 Petition at 6. Petitioner offers as an example a tweet and video that Petitioner states were posted on the @CDCDirector Twitter account. Petitioner asserts that, in the video, the Director of the CDC states "[w]e now know based on rigorous scientific review that the vaccines available here in the United States can be used safely and effectively in children under 5" and "[w]e have taken another important step together on our fight against COVID-19 by making safe and effective vaccines available for our little ones." August 2022 Petition at 6. Petitioner asserts that the tweet is "'descriptive printed matter, advertising, and promotional material' because it promotes COVID-19 vaccination for children" and "[t]herefore, the tweet violates the Pfizer and Moderna EUAs as it failed to include the language required by the EUA Advertising Conditions." August 2022 Petition at 6-7. As another example, Petitioner asserts that "HHS launched a series of ad campaigns promoting the COVID-19 vaccines for infants and children" on YouTube which purportedly state that "[i]f your child is 6 months old and older, you can now help protect them from severe COVID illness by getting them a COVID vaccine." August 2022 Petition at 7-8. Petitioner asserts that the "HHS video is 'descriptive printed matter, advertising, and promotional material' and violates both Pfizer's and Moderna's EUAs because it fails to include the language required by the conditions of those EUAs." August 2022 Petition at 8. Petitioner also provides a list of what Petitioner describes as "examples of federal and state health agencies ignoring the EUA-required conditions" and referencing emails, webpages, and Facebook pages posted by a variety of organizations. August 2022 Petition at 8. Petitioner asserts that "all lacked the language required by the EUA Advertising Conditions. Therefore, all of the promotions were in violation of the EUAs." August 2022 Petition at 8-9.

Petitioner concludes that "the best course of action is for the FDA to amend the EUAs to remove the EUA Advertising Condition since the FDA plainly does not intend to enforce this condition." August 2022 Petition at 9. To support the request for removal of these conditions of authorization from the letters of authorization for the COVID-19 vaccines, Petitioner argues that "FDA's continued inaction regarding this matter is an implied approval of widespread, ongoing conduct that violates federal law" and that the "public interest weighs strongly in favor of the requested relief because the FDA's failure to enforce the EUAs' 'Conditions of Authorization' sows doubt in the American consumer slated to receive these EUA products and sows distrust in the FDA as an agency that does not enforce its own conditions." August 2022 Petition at 9.

To the extent the August 2022 Petition takes issue with FDA's enforcement approach, as described above, FDA's decisions with respect to enforcement action or related regulatory activity are within the discretion of the Agency and are made on a case-by-case basis. To the extent the August 2022 Petition is based on a "public interest" rationale, this rationale is that the EUA conditions have given rise to "an implied approval of widespread, ongoing conduct that violates federal law" that has or would "sow[] doubt in the American consumer" and "sow[] distrust in the FDA as an agency." However, the Petitioner's assertion that the EUA conditions have caused doubt or distrust is unsupported. The August 2022 Petition does not provide support for the assertion that the EUA conditions have "sow[n] doubt in the American consumer" or "sow[n] distrust in the FDA as an agency." Thus, the Petition has not provided a factual basis for the "public interest" rationale. Similarly, the Petition has not provided information demonstrating that the requested action (revocation of the EUA conditions) would address any alleged doubt or lack of trust. Accordingly, the Petition has both failed to make a factual showing regarding the connection between the EUA conditions and the existence of any "doubt" and "distrust," and has also failed to show that the requested action would cure the asserted harm. Therefore, the August 2022 Petition has not shown that granting the requested action would solve the alleged problem that the Petition identifies. In addition, as stated above, under section 564(e)(4) of the FD&C Act, one discretionary condition that FDA may place in EUAs is a condition on advertisements and other promotional descriptive printed matter (e.g., press releases issued by the EUA sponsor) relating to the use of an EUA product, such as requirements applicable to prescription drugs under section 502(n). The conditions related to printed matter and promotional material in the COVID-19 vaccine EUAs are consistent with section 564(e)(4), in that the conditions establish requirements for advertisements and other promotional descriptive matter relating to the use of an EUA product. Although FDA may choose to revise these conditions as it determines to be appropriate, the August 2022 Petition does not identify any *legal requirement* for FDA to remove this condition of authorization from any of the Authorized COVID-19 Vaccines as requested. For these reasons, FDA denies this request.

III. CONCLUSION

FDA has considered Petitioner's requests relating to the EUAs for the vaccines to prevent COVID-19. For the reasons given in this letter, FDA denies the requests and therefore denies the Petitions in their entirety.

Sincerely,

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

cc: Dockets Management Staff