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VIA ONLINE PORTAL

September 24, 2021

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane,
Rm. 1061
Rockville, MD 20852

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES AND THE FOOD AND DRUG ADMINISTRATION

PETITION FOR ADMINISTRATIVE ACTION REGARDING EMERGENCY USE AUTHORIZATIONS GRANTED TO MODERNA AND JANSSEN COVID-19 VACCINES :
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:
: **Docket No.**_____

CITIZEN PETITION

This petition for administrative action is submitted on behalf of Informed Consent Action Network (“**Petitioner**”) pursuant to 21 C.F.R. § 10.30 and related and relevant provisions of law (including the Federal Food, Drug and Cosmetic Act or the Public Health Service Act) to request that the Commissioner of Food and Drugs (the “**Commissioner**”) revoke the Emergency Use Authorization (“**EUA**”) granted to ModernaTx, Inc. (EUA 27073), and Janssen Biotech, Inc. (EUA 27205) concerning their respective COVID-19 vaccines pursuant to 21 U.S.C. § 360bbb-3 (the “**EUA Statute**”).

On August 23, 2021, the FDA granted approval to the Pfizer-BioNTech COVID-19 Vaccine, Comirnaty, for the prevention of COVID-19 disease in individuals 16 years of age or older.¹ The EUA Statute states that one of the criteria for the grant or continuation of an EUA is that there is “no adequate, approved, and available alternative to the product.” 21 U.S.C. § 360bbb-3(c)(3). Given that there is now an “adequate, approved, and available alternative” to the Moderna and Janssen COVID-19 vaccines, statutorily required conditions to continue the EUAs granted to these vaccines no longer exist. Therefore, Petitioner respectfully requests that the Commissioner

¹ See <https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine>.

act on the instant Petition and revoke the EUAs granted to ModernaTx, Inc., and Janssen Biotech, Inc. for their COVID-19 vaccines.

A. ACTION REQUESTED

1. It is hereby requested that the EUAs granted to ModernaTx, Inc., and Janssen Biotech, Inc for their COVID-19 vaccines be revoked.

B. STATEMENT OF GROUNDS

2. Under the EUA Statute, one of the core conditions that must exist for the grant² or continuation³ of an EUA is that there be “no adequate, approved, and available alternative to the product” in question. 21 U.S.C. § 360bbb-3(c)(3). If there is an “adequate, approved, and available” COVID-19 vaccine, the conditions for permitting EUAs for other COVID-19 vaccines are no longer met.

3. In the EUA Authorization letters issued to ModernaTx, Inc., the FDA made an express finding to justify the grant of the emergency use authorization that “[t]here is no adequate, approved, and available alternative to the emergency use of Moderna COVID-19 Vaccine to prevent COVID-19.”⁴ The FDA made a similar finding in the EUA Authorization letters addressed to Janssen Biotech, Inc.⁵

4. On August 23, 2021, the FDA granted approval to the Pfizer-BioNTech COVID-19 Vaccine, Comirnaty, for the prevention of COVID-19 disease in individuals 16 years of age or older.⁶

5. Upon the FDA’s approval of Comirnaty, Petitioner understood that the FDA would withdraw its EUAs for the Moderna and Janssen COVID-19 vaccines since there was now an adequate, approved, and available COVID-19 vaccine, Comirnaty, and the conditions of 21 U.S.C. § 360bbb-3(c)(3) were no longer met.⁷

² See <https://www.fda.gov/media/142749/download>.

³ See <https://www.fda.gov/media/147629/download>.

⁴ <https://www.fda.gov/media/144673/download>; <https://www.fda.gov/media/144636/download>.

⁵ See <https://www.fda.gov/media/146338/download>; <https://www.fda.gov/media/146303/download>.

⁶ See <https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine>.

⁷ ICAN, through Mr. Siri, initially sought to resolve this issue informally through an e-mail exchange with Dr. Woodcock, the Acting Commissioner of the FDA, and Dr. Marks, Director of the FDA’s Center for Biologics Evaluation and Research. However, **when pressed to substantiate its position that there was not an adequate, approved, and available alternative to Moderna and Janssen’s COVID-19 vaccines, the FDA advised that “we consider this e-mail conversation to be closed.”** See **Exhibit A** for the email exchange between ICAN’s counsel, Dr. Marks, and Ms. Lorrie McNeill. Hence, ICAN was forced to file the current petition.

6. Comirnaty is an approved alternative. Since the United States currently has a large surplus⁸ of Pfizer's COVID-19 vaccines, with Pfizer ramping up production,⁹ then Comirnaty is also an adequate and available alternative and, hence, the requirements under federal law for continuing the EUA for Moderna and Janssen's COVID-19 vaccines are no longer satisfied.

7. Despite this, on September 1, 2021, Dr. Peter Marks stated, in relevant part:¹⁰

...the FDA may issue an EUA after the agency determines that the following statutory requirements are met (section 564 of the Food, Drug & Cosmetic Act [21 U.S.C. § 360bbb-3]):

- The chemical, biological, radiological, or nuclear (CBRN) agent referred to in the EUA declaration by the Secretary of HHS (SARS-CoV-2) can cause a serious or life-threatening disease or condition (COVID-19).
- Based on the totality of scientific evidence available to FDA, including data from adequate and well controlled trials, if available, it is reasonable to believe that the product may be effective to prevent, diagnose, or treat COVID-19.
- 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.

If a COVID-19 vaccine is licensed (approved) by the FDA, that would not automatically preclude issuance or continuation of an EUA for another COVID-19 vaccine, taking into account the statutory criteria for EUAs. At this time, the agency will not be withdrawing the EUAs for the Moderna and Janssen COVID-19 vaccines.

8. ICAN agrees that licensure of one COVID-19 vaccine does not automatically preclude continuance of the EUAs for other COVID-19 vaccines (e.g., if the licensed COVID-19 vaccine was for one age group while the EUA vaccines were for a different age group, the EUA would still meet all necessary criteria as there is no alternative.). However, the FDA must take into account the statutory criteria for EUAs, and here, the existence of an approved COVID-19

⁸ See <https://www.statnews.com/2021/07/20/states-are-sitting-on-millions-of-surplus-covid-19-vaccine-doses-as-expiration-dates-approach/>.

⁹ See <https://www.wsj.com/articles/pfizer-lifts-covid-19-vaccine-production-targets-for-2021-2022-11620425904#:~:text=Pfizer%20expects%20to%20produce%203,on%20social%2Dmedia%20site%20LinkedIn.>

¹⁰ Exhibit A.

vaccine, Comirnaty, is an “adequate, approved, and available alternative” vis-a-vis the other EUA COVID-19 vaccines.

9. Ms. Lorrie H. McNeill, Director, Office of Communication, Outreach and Development, CBER, stated on September 7, 2021, in relevant part:

Consistent with our statutory obligations and the policies set forth in our guidance concerning emergency use of medical products, **FDA periodically reviews the circumstances and the appropriateness of an EUA authorization, including circumstances that might warrant revocation of the EUA.** The review will include regular assessment, based on additional information provided by the sponsor, of the progress made with respect to the approval, licensure, or clearance of the unapproved product, or of the unapproved use of an approved product, for which an EUA was issued.

If a COVID-19 vaccine is licensed (approved) by the FDA, the statute does not automatically preclude issuance or continuation of an EUA. The Agency may revise or revoke an EUA if the circumstances justifying its issuance no longer exist, or other circumstances make a revision or revocation appropriate to protect the public health or safety. See section 564(g)(2) of the FD&C Act. The milestone licensure for the Pfizer COVID-19 vaccine, COMIRNATY, provides the American people with an approved option for vaccination. **The Agency has determined that the EUAs for the authorized vaccines to prevent COVID-19 should remain in place at this time.** Although COMIRNATY (COVID-19 Vaccine, mRNA) is approved to prevent COVID-19 in individuals 16 years of age and older, **there is not currently sufficient approved vaccine available for distribution to this population in its entirety.** Additionally, there are no products that are approved to prevent COVID-19 in individuals age 12 through 15, or that are approved to provide an additional dose to the immunocompromised population described in this EUA.^[11] All of the approved and authorized COVID-19 vaccines have been shown to meet the Agency’s high standards of safety and effectiveness.¹²

10. Despite the FDA’s statement that “there is not currently sufficient approved vaccine available for distribution to this population in its entirety,” the CDC’s data and Pfizer’s public

¹¹ Petitioner agrees that the EUA for the use of the Pfizer vaccine in those ages 12 through 15 and in the immunocompromised population still arguably meets the conditions of the EUA statute. Petitioner requests that only the EUAs for the Moderna and Janssen COVID-19 vaccines are revoked as those no longer meet the conditions of the EUA statute (as the populations covered by these vaccines are now covered by the adequate, approved, and available Comirnaty vaccine).

¹² Exhibit A.

statements reflect 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.¹³ Given the current rate of daily vaccination in the United States (which was 710,207 doses on average per day for the last three months¹⁴), it is unclear on what basis the FDA is claiming that there is insufficient supply of Pfizer’s vaccine for distribution to those 16 years of age and older in the United States.

11. If the average daily demand for COVID-19 vaccine in the United States continues at around 700,000 doses per day, then 85 million doses would be sufficient to meet demand for the next 121 days. Adding an additional 200 million doses that Pfizer is to deliver to the United States over the coming months, the daily demand should be met for the foreseeable future. (This ignores the additional 500 million doses of Pfizer vaccine the U.S. is purchasing for distribution to other countries.)

12. Given this, the FDA cannot claim that “there is not currently sufficient approved vaccine availability for distribution to” those 16 years of age and older when there is currently enough supply to meet daily demand.

13. On September 14, 2021, Ms. McNeill reiterated the agency’s position that the EUAs for COVID-19 vaccines would not be revoked “...based on our determination, the current COVID-19 vaccine emergency use authorizations are appropriate at this time” but again failed to explain how it can claim there is insufficient supply of the Pfizer vaccine in the United States to meet demand.¹⁵

14. Because the criteria for the issuance of an EUA are no longer met with respect to Moderna’s and Janssen’s COVID-19 vaccines, Petitioner requests that the EUAs for Moderna’s and Janssen’s COVID-19 vaccines be revoked forthwith.

C. ENVIRONMENTAL IMPACT

15. The undersigned hereby states that the relief requested in this petition will have no environmental impact and therefore an environmental assessment is not required under 21 C.F.R. Sections 25.30 and 25.31.

D. ECONOMIC IMPACT

16. Economic impact information will be submitted upon request of the commissioner.

¹³ See CDC’s COVID Data Tracker available at https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total; see also Pfizer’s Press Releases available at <https://www.pfizer.com/news/press-release/press-releases-archive>.

¹⁴ See CDC Data available at <https://data.cdc.gov/Vaccinations/COVID-19-Vaccination-Trends-in-the-United-States-N/rh2h-3yt2>.

¹⁵ Exhibit A.

E. CERTIFICATION

17. The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

18. The Petitioner therefore respectfully urges that this request be granted forthwith.

Respectfully submitted,

/s/ Aaron Siri

Aaron Siri

Elizabeth A. Brehm

SIRI & GLIMSTAD LLP

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17th Floor

New York, NY 10166

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Email: aaron@sirillp.com

EXHIBIT A

Aaron Siri

From: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Sent: Tuesday, September 14, 2021 2:58 PM
To: Aaron Siri
Cc: Woodcock, Janet; Marks, Peter; Maloney, Diane; Tierney, Julia
Subject: RE: [EXTERNAL] Will the EUA for Moderna and J&J be rescinded?

Dear Mr. Siri,

With regard your inquiry concerning the “recent response,” we refer you to the Agency’s response dated September 1, 2021 from Dr. Peter Marks.

As stated in our prior correspondences, based on our determination, the current COVID-19 vaccine emergency use authorizations are appropriate at this time. The Agency intends to periodically review the circumstances and the appropriateness of each EUA, including circumstances that might warrant revocation of an EUA.

FDA continues its critical work to protect public health during the COVID-19 pandemic. As you are undoubtedly aware, the current major public health crisis and the urgency of the issues it entails demand our full attention. It is thus necessary for the Agency to prioritize these issues and its responses to inquiries. Accordingly, we consider this e-mail conversation to be closed. We appreciate your understanding.

Best Regards,

Lorrie

Lorrie H. McNeill

Director

Office of Communication, Outreach and Development
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration
lorrie.mcneill@fda.hhs.gov



From: Aaron Siri <aaron@sirillp.com>
Sent: Monday, September 13, 2021 10:55 PM
To: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Cc: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Maloney, Diane <Diane.Maloney@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: [EXTERNAL] Will the EUA for Moderna and J&J be rescinded?

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Dear Ms. McNeill,

Can you kindly let me know the FDA's position on the question below.

Thank you,
Aaron

From: Aaron Siri

Sent: Thursday, September 9, 2021 7:23 PM

To: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>

Cc: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Maloney, Diane <Diane.Maloney@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>

Subject: RE: [EXTERNAL] Will the EUA for Moderna and J&J be rescinded?

Dear Ms. McNeill,

For those falling within the indicated use for Pfizer's Comirnaty, you indicate that the EUA will not be withdrawn for other Covid-19 vaccines because "there is not currently sufficient approved vaccine available for distribution to this population in its entirety." However, the CDC's data and Pfizer's public statements reflect 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. See [CDC's COVID Data Tracker](#) and [Pfizer Press Releases](#). Given the current rate of daily vaccination in the United States (which was 710,207 doses on average per day for the last three months, see [CDC Data](#)), it is unclear on what basis the FDA is claiming that there is insufficient supply of Pfizer's vaccine for distribution to those 16 years of age and older in the United States.

If the average daily demand for Covid-19 vaccine in the United States continues at around 700,000 doses per day, then 85 million doses would be sufficient to meet demand for the next 121 days. Adding an additional 200 million doses that Pfizer is to deliver to the United States over the coming months, the daily demand should be met for the foreseeable future. (This ignores the additional 500 million doses of Pfizer vaccine the U.S. is purchasing for distribution to other countries.)

Please advise if the FDA contests the CDC's data reflecting approximately 32 million doses of Pfizer vaccine delivered but not yet administered in the United States, and that the U.S. Government has approximately 50 million additional doses it could distribute, and that the U.S. Government has another 200 million doses scheduled for delivery from Pfizer in the coming months. If the FDA does not contest these figures, **please explain how the FDA can claim "there is not currently sufficient approved vaccine availability for distribution to" those 16 years of age and older when there is currently enough current supply to meet daily demand?**

As an aside, your email indicates that you provided a "recent response," but I never received any such recent response – can you kindly forward same.

Thank you.

Best regards,
Aaron

From: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>

Sent: Tuesday, September 7, 2021 3:16 PM

To: Aaron Siri <aaron@sirillp.com>

Cc: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Maloney, Diane <Diane.Maloney@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>

Subject: RE: [EXTERNAL] Will the EUA for Moderna and J&J be rescinded?

Dear Mr. Siri,

This is in response to your email dated September 1, 2021. As previously noted in my recent response, under appropriate circumstances, FDA may issue an emergency use authorization (EUA) to allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent COVID-19. FDA may issue an EUA after the Agency determines that the statutory requirements under section 564 of the Food, Drug & Cosmetic Act (FD&C Act) are met.

Consistent with our statutory obligations and the policies set forth in our guidance concerning emergency use of medical products,^[1] FDA periodically reviews the circumstances and the appropriateness of an EUA authorization, including circumstances that might warrant revocation of the EUA. The review will include regular assessment, based on additional information provided by the sponsor, of the progress made with respect to the approval, licensure, or clearance of the unapproved product, or of the unapproved use of an approved product, for which an EUA was issued.

If a COVID-19 vaccine is licensed (approved) by the FDA, the statute does not automatically preclude issuance or continuation of an EUA. The Agency may revise or revoke an EUA if the circumstances justifying its issuance no longer exist, or other circumstances make a revision or revocation appropriate to protect the public health or safety. See section 564(g)(2) of the FD&C Act.

The milestone licensure for the Pfizer COVID-19 vaccine, COMIRNATY, provides the American people with an approved option for vaccination. The Agency has determined that the EUAs for the authorized vaccines to prevent COVID-19 should remain in place at this time. Although COMIRNATY (COVID-19 Vaccine, mRNA) is approved to prevent COVID-19 in individuals 16 years of age and older, there is not currently sufficient approved vaccine available for distribution to this population in its entirety. Additionally, there are no products that are approved to prevent COVID-19 in individuals age 12 through 15, or that are approved to provide an additional dose to the immunocompromised population described in this EUA. All of the approved and authorized COVID-19 vaccines have been shown to meet the Agency's high standards of safety and effectiveness.

I hope this information is helpful.

Best regards,

Lorrie

Lorrie H. McNeill

Director

Office of Communication, Outreach and Development
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration
lorrie.mcneill@fda.hhs.gov



From: Marks, Peter <Peter.Marks@fda.hhs.gov>

Sent: Thursday, September 2, 2021 11:55 AM

To: Aaron Siri <aaron@sirillp.com>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>

Cc: Maloney, Diane <Diane.Maloney@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>

Subject: RE: [EXTERNAL] Will the EUA for Moderna and J&J be rescinded?

Dear Mr. Siri,

My apologies for the delay, but we are currently involved in a major public health pandemic response. We are doing our best to respond to your messages timely. Since our replies may find their way into the public domain, they need to be cleared by our Office of Chief Counsel. As soon as our reply to your last message clears our Office of Chief Counsel, we will forward it promptly.

Best Regards,
Peter

Peter Marks, MD, PhD
Director
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration
10903 New Hampshire Avenue
WO71-7232
Silver Spring, MD 20993
240-402-8116 voice
301-595-1310 fax
Peter.Marks@fda.hhs.gov

From: Aaron Siri <aaron@sirillp.com>

Sent: Thursday, September 2, 2021 11:41 AM

To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>

Cc: Maloney, Diane <Diane.Maloney@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>

Subject: RE: [EXTERNAL] Will the EUA for Moderna and J&J be rescinded?

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Good morning Dr. Marks,

Can you please let me know if it is the FDA's position that Comirnaty is not an adequate, approved and available alternative to the current EUA Covid-19 vaccines?

Thank you,
Aaron

From: Aaron Siri

Sent: Wednesday, September 1, 2021 8:53 AM

To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>

Cc: Maloney, Diane <Diane.Maloney@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>

Subject: RE: [EXTERNAL] Will the EUA for Moderna and J&J be rescinded?

Dr. Marks,

Thanks for the response but it does not address the point we raised.

We certainly agree that licensure of one Covid-19 vaccine does not automatically preclude continuance of the EUAs for other Covid-19 vaccines. (For example, if the licensed Covid-19 vaccine was for one age group while the EUA vaccines were for a different age group.) But, as you point out, the FDA must take into account the statutory criteria for EUAs, and here, the existence of a licensed Covid-19 vaccine, Comirnaty, is, as far as we can see, an “adequate, approved, and available alternative” vis-a-vis the other EUA Covid-19 vaccines.

Is it the FDA’s position that Comirnaty is not an adequate, approved and available alternative to the EUA Covid-19 vaccines?

Thank you,
Aaron

From: Marks, Peter <Peter.Marks@fda.hhs.gov>

Sent: Wednesday, September 1, 2021 7:10 AM

To: Aaron Siri <aaron@sirillp.com>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>

Cc: Maloney, Diane <Diane.Maloney@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>

Subject: RE: [EXTERNAL] Will the EUA for Moderna and J&J be rescinded?

Dear Mr. Siri,

This is in response to your email of August 23, 2021 asking that FDA “confirm” that the Emergency Use Authorizations (EUAs) for Moderna COVID-19 Vaccine and Janssen COVID-19 Vaccine will be withdrawn following the approval of Comirnaty (COVID-19 Vaccine, mRNA).

On the basis of the determination by the Secretary of the Department of Health and Human Services on February 4, 2020, that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and then issued declarations that circumstances exist justifying the authorization of emergency use of unapproved products, the FDA may 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 COVID-19 when there are no adequate, approved, and available alternatives.

Based on this declaration and determination, the FDA may issue an EUA after the agency determines that the following statutory requirements are met (section 564 of the Food, Drug & Cosmetic Act [21 U.S.C. 360bbb-3]):

- The chemical, biological, radiological, or nuclear (CBRN) agent referred to in the EUA declaration by the Secretary of HHS (SARS-CoV-2) can cause a serious or life-threatening disease or condition (COVID-19).
- Based on the totality of scientific evidence available to FDA, including data from adequate and well controlled trials, if available, it is reasonable to believe that the product may be effective to prevent, diagnose, or treat COVID-19.
- 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.

If a COVID-19 vaccine is licensed (approved) by the FDA, that would not automatically preclude issuance or continuation of an EUA for another COVID-19 vaccine, taking into account the statutory criteria for EUAs. At this time, the agency will not be withdrawing the EUAs for the Moderna and Janssen COVID-19 vaccines.

I hope this information is helpful.

Best Regards,

Peter Marks

Peter Marks, MD, PhD
Director
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Peter.Marks@fda.hhs.gov



From: Aaron Siri <aaron@sirillp.com>
Sent: Wednesday, September 1, 2021 9:47 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Maloney, Diane <Diane.Maloney@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Subject: RE: [EXTERNAL] Will the EUA for Moderna and J&J be rescinded?

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Good morning Dr. Marks,

Thank you for the acknowledgment eight days ago that a formal response will be forthcoming.

Absent same by end of day today, we have been directed to file a formal petition.

Thank you.

Best regards,
Aaron

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Tuesday, August 24, 2021 1:48 AM
To: Aaron Siri <aaron@sirillp.com>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Maloney, Diane <Diane.Maloney@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Subject: RE: [EXTERNAL] Will the EUA for Moderna and J&J be rescinded?

Dear Mr. Siri,

We acknowledge your message of August 23, 2021. A formal response will be forthcoming.

Best Regards,
Peter Marks

Peter Marks, MD, PhD
Director
Center for Biologics Evaluation and Research
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Silver Spring, MD 20993
240-402-8116 voice
301-595-1310 fax
Peter.Marks@fda.hhs.gov

From: Aaron Siri <aaron@sirillp.com>
Sent: Monday, August 23, 2021 8:49 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: [EXTERNAL] Will the EUA for Moderna and J&J be rescinded?
Importance: High

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Good evening Dr. Woodcock and Dr. Marks,

Now that there is an adequate, approved and available COVID-19 vaccine licensed by the FDA, the conditions for continuing the EUAs for Moderna and J&J Covid-19 vaccines are no longer satisfied.

As you are aware, under [federal law](#) a condition for [granting](#) and [continuing](#) an EUA for a COVID-19 vaccine is that there must be “no adequate, approved, and available alternative.” If there is an “adequate, approved, and available” COVID-19 vaccine, the conditions for permitting EUAs for other COVID-19 vaccines are no longer met.

Since Pfizer’s Covid-19 vaccine has now been approved, and the United States currently has a large [surplus](#) of COVID-19 vaccines with Pfizer ramping up [production](#), the requirements under federal law for continuing the EUA for Moderna and J&J’s Covid-19 vaccines are no longer satisfied.

Hence, kindly confirm that the FDA will be withdrawing its EUAs for the Moderna and J&J Covid-19 vaccines.

In writing directly, the hope is to avoid the need for a formal petition on this matter.

Thank you.

Best regards,
Aaron

Aaron Siri, Esq.
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^[1] See section 564(g)(1) of the FD&C Act; “Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders,” *available at* <https://www.fda.gov/media/97321/download>