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VIA ONLINE PORTAL

September 27, 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	**:**	**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 Statue**").

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 grant[2] or continuation[3] 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]

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[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 surplus[8] 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

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[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 months[14]), 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.

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[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,

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