DEPARTMENT OF THE AIR FORCE
AIR FORCE RESERVE COMMAND

17 March 2022

MEMORANDUM FOR [redacted]OSS/CC

FROM: MAJ ERIC COULTER

SUBJECT: Medical Exemption Request from COVID-19 Vaccination for Lack of Supply (MS)

References: (a) AFI 48-110_IP, *Immunizations and Chemoprophylaxis for the Prevention of Infectious Diseases*, 7 Oct 2013 (certified current 16 Feb 2018)
(b) Secretary of Defense, *Mandatory Coronavirus Disease 2019 Vaccination of Department of Defense Service Members Memorandum*, 24 Aug 2021
(c) Secretary of the Air Force, *Mandatory Coronavirus Disease 2019 Vaccination of Department of the Air Force Military Members Memorandum*, 3 Sep 2021
(d) [redacted] OSS Commander, *Initial Order to Receive Mandatory COVID-19 Vaccine*, 16 Oct 2021
(e) through (p), see Attachment 1

1. I, Major Eric A. Coulter, [redacted], DOD ID [redacted], request a 90-day Medical Exemption for supply (MS) in accordance with AFI 48-110_IP (Section 2-6, subsection a. and appendix C) (reference (a)) from vaccination for Coronavirus Disease 2019 due to the unavailability of an FDA-approved (BLA-licensed) vaccine. This exemption request is supported by the details below.

2. On 24 August 2021, the Secretary of Defense (SecDef) released a memorandum (reference (b)) directing all service members to begin vaccination of all members of the Armed Forces, indicating that the mandatory vaccination will "only use COVID-19 vaccines that receive full licensure from the Food and Drug Administration (FDA), in accordance with FDA-approved labeling and guidance. Service members voluntarily immunized with a COVID-19 vaccine under FDA Emergency Use Authorization or World Health Organization Emergency Use Listing…are considered fully vaccinated."

3. On 3 September 2021, the Secretary of the Air Force (SecAF) reiterated the SecDef's guidance in his own memorandum (reference (c)), stating "commanders in the Department of the Air Force shall take all steps necessary to ensure all uniformed Airmen and Guardians receive the COVID-19 vaccine" but caveats this statement in his memo stating "only COVID-19 vaccines that receive full licensure from the Food and Drug Administration (FDA) will be utilized for mandatory vaccination unless a military member volunteers to receive a vaccine that has obtained U.S. Food and Drug Administration Emergency Use Authorization or is

included in the World Health Organization's Emergency Use Listing".

4. On 16 October, I received an initial order from you (reference (d)) ordering me to "receive an initial dose of a COVID-19 vaccine with full licensure approval from the FDA" by 18 Oct 2021. You stipulate that in accordance with a 14 Sep 2021 memorandum from the Assistant Secretary of Defense for Health Affairs (ASD(HA)) that "the Pfizer-BioNTech COVID-19 vaccine (aka the Pfizer vaccine) has the same formulation as the COMIRNATY COVID-19 vaccine and is considered interchangeable for vaccine requirement purposes." As we had discussed in the days leading up to your written order, I informed you of my intent to submit a Religious Accommodation Request (RAR) to the COVID-19, annotated such on the order and submitted the RAR on 17 Oct 2021.

5. On 3 Dec 2021, you and I sat down for an in-person meeting where you gave me a copy of the disapproval of my RAR from the Air Force Reserve Command Commander (AFRC/CC) which does not differentiate between the "recently approved COMIRNATY®/ Pfizer-BioNTech COVID-19 vaccine" instead calling out other "EUA COVID-19 vaccines that include Johnson's Janssen and the Moderna COVID-19 vaccines." In that meeting you reiterated that your standing written order from 16 Oct 2021 was still in effect and that I had 72 hours to either be vaccinated or appeal the AFRC/CC's disapproval to the Air Force Surgeon General (HAF/SG). I chose to make an appeal and submitted it on 6 Dec 2021.

6. On 12 March 2022, you and I had a video call where you informed me of HAF/SG's denial of my RAR, provided me his memo from 25 Feb 2022 and issued me a new written order (reference (e)) to be vaccinated. In it you order me to "**receive an initial dose of a COVID-19 vaccine with full licensure approval from the FDA AND provide proof by 17 Mar 2022.**" Though that statement seems cut and dry, other parts of your order discuss the ASD(HA) guidance referenced in your original order and you state that "The Pfizer COVID-19 vaccine is not the only option available for complying with this order. Alternatively, you may choose to receive the two-shot Moderna COVID-19 vaccine or the single shot J&J COVID-19 vaccine. If you choose to receive the Moderna series vaccine, you must comply with the two deadlines listed above. If you choose to receive the J&J vaccine, you must comply with the first deadline listed above." **The difference between the order and the other statements are the crux of my request for medical exemption.**

7. The ASD(HA) memorandum dated 14 Sep 2021 (reference directs that "consistent with FDA guidance, DoD health care providers will use both the Pfizer-BioNTech COVID-19 vaccine and the COMIRNATY COVID-19 vaccine interchangeably for the purpose of vaccinating Service members" in accordance with the SecDef Memo (reference (a)), while also referencing an FDA Q&A website which was accessed on 10 Sep 2021. The website referenced by the ASD(HA) has changed since then, but fortunately archived versions are available (reference (f)). The Q&A website does indeed state that FDA-approved (or BLA-licensed) Pfizer-BioNTech COMIRNATY and the FDA-authorized Pfizer-BioNTech COVID-19 Vaccine under Emergency Use Authorization (EUA) "have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series without presenting any safety or effectiveness concerns." Where the FDA Q&A differs from the ASD(HA) memo is that it states that "providers **can** use doses distributed under EUA to administer the vaccination

series as if the doses were the licensed vaccine", whereas the ASD(HA) memo asserts "DoD health care providers **should** 'use doses distributed under the EUA to administer the vaccination series as if the doses were the licensed vaccine'" when referencing the website. The verbiage on the FDA website continues to differentiate between FDA-approved (BLA-licensed) COMIRNATY and the EUA Pfizer-BioNTech COVID-19 Vaccine, going so far as stating "COMIRNATY has the same formulation as the FDA-authorized Pfizer-BioNTech COVID-19 vaccine and can be used interchangeably to provide the COVID-19 vaccination series without presenting any safety or effectiveness concerns. ***The products are legally distinct with certain differences that do not impact safety or effectiveness****"* to the question "Is COMIRNATY Vaccine interchangeable with other COVID-19 vaccines?".

8. The confusion of the interchangeability not only leads to confusion with your order, but also with newly released COVID-19 Mandatory Vaccination Implementation Guidance for DAF Service Members released by the Deputy Director of Staff for COVID-19 on 14 Mar 2022 (reference (g)). In Chapter 1 (Introduction), section 1.2.1, COMIRNATY and the EUA Pfizer-BioNTech COVID-19 Vaccine are deemed "interchangeable" with verbiage very similar to that used in the ASD(HA) memorandum (reference (f)), but does not reference that memorandum. In section 1.2.2, SPIKEVAX is also claimed to be "interchangeable" with the EUA Moderna COVID-19 Vaccine and that "DoD health care providers should 'use doses distributed under the EUA to administer the vaccination series as if the doses were the licensed vaccine.'" This verbiage and recommendation are not contained in the ASD(HA) memo, though it appears the same logic is used has been used. What is perplexing is in Chapter 3 (Education Plan for Mandatory Vaccination), the Implementation Guidance reverses those statements saying in section 3.1.1 that "The Comirnaty (Pfizer) and Spikevax (Moderna) vaccines are FDA-approved for the prevention of severe COVID-19 disease, hospitalization, and death." Additionally in section 3.1.3, the guidance returns to SecDef and SecAF guidance that "Only an FDA-licensed vaccine may be mandated; however, Service members may be voluntarily immunized with any FDA approved or authorized COVID-19 vaccine or WHO EUL COVID-19 vaccine prior to or after the establishment of this policy and are considered fully vaccinated."

9. A Frequently Asked Questions document (reference (h)) intended to accompany the COVID-19 Mandatory Vaccination Implementation Guidance for DAF Service Members extends the schizophrenic nature of the guidance. The answer to question 19 "What if the vaccine on my base is not licensed by the FDA? Can I be forced to be vaccinated?" the FAQ answers "To comply with the mandate, Service members may elect to receive any COVID-19 vaccine that is FDA-approved, has an FDA Emergency Use Authorization (EUA), or is on the World Health Organization (WHO) Emergency Use Listing (EUL). Service members may only be compelled to take FDA-approved vaccines. Currently, Comirnaty (Pfizer) and Spikevax (Moderna) are FDA-approved. If supplies are limited, members can choose to get vaccinated on their own or wait for adequate supply at a DoD facility. MTFs will have adequate vaccine supplies to meet the SecAF's vaccination timeline." The answer to question 34 "Can I choose which type of vaccine to take (Pfizer, J&J, Moderna)?" initially reiterates the answer from question 19, but then shifts back to guidance similar to the ASD(HA) memo (reference (f)) stating "The Comirnaty (Pfizer) vaccine has the same formulation as the Pfizer-BioNTech COVID-19 vaccine distributed under the EUA and therefore both vaccines can be used interchangeably. Likewise, the Spikevax (Moderna)

vaccine has the same formulation as the Moderna COVID-19 vaccine distributed under the EUA and therefore both vaccines can be used interchangeably."

10. The sheer amount of continued confusion points to a need to look at the "interchangability" of the EUA COVID-19 vaccines with FDA-approved (BLA-licensed) more closely. The use of a Q&A website as definitive proof of interchangeability is strange given the rigorous processes the FDA uses in determining what is fully approved (BLA-licensed) and EUA-authorized. The FDA source database which "contains information about all FDA-licensed biological products regulated by the Center for Drug Evaluation and Research (CDER), including licensed biosimilar and interchangeable products, and their reference products" is the FDA's Purple Book (https://purplebooksearch.fda.gov). A search of the database for "covid" returns two Reference Products, BioNTech Manufacturing GmbH's COMIRNATY COVID-19 Vaccine, mRNA (BLA 125742) and ModernaTX Inc's SPIKEVAX COVID-19 Vaccine, mRNA (BLA 125752) (attachment 2). In addition, the database shows no Biosimilars and no Interchangeables (attachment 3 and 4). These two Reference Products match with the FDA approval letters on 23 Aug 2021 for COMIRNATY (with a supplemental approval on 16 Dec 2021) (reference (i) and (j)) and 31 Jan 2022 for SPIKEVAX (reference (k)).

11. In the FDA approval letters for both COMIRNATY and SPIKEVAX, there is no mention of equivalency of the EUA authorized vaccines. On the other hand, the reissued Letter of Authorization for Emergency Use for the Pfizer-BioNTech COVID-19 Vaccine dated 3 Jan 2022 (reference (l)), repeatedly references the FDA approval of COMIRNATY, while restating the emergency authorization of the Pfizer-BioNTech COVID-19 Vaccine and certain uses (for individuals 12-16) of COMIRNATY (COVID-19 Vaccine mRNA). It also makes the same statements which used to appear on the FDA Q&A website for COMIRNATY that "The products are legally distinct with certain differences that do not impact safety or effectiveness." Similarly, the reissued Letter of Authorization for Emergency Use for the Moderna COVID-19 Vaccine dated 15 Mar 2022 (reference (m)), repeatedly references the FDA approval of SPIKEVAX, while restating the emergency authorization of the Moderna COVID-19 Vaccine. As with the Pfizer EUA letter, it also states that "The products are legally distinct with certain differences that do not impact safety or effectiveness."

12. The final source I'll point to regarding the difference between the FDA approved (BLA-licensed) and EUA vaccines is the Center for Disease Control (CDC) Immunization Information System (IIS) Data Code Database for COVID-19 Vaccine Related Codes (https://www.cdc.gov/vaccines/programs/iis/COVID-19-related-codes.html). The website (attachment 5) "provides a summary of the currently authorized vaccine codes and a preview of the vaccine codes that will be activated if the FDA authorizes use". The data table lists vaccine by name and National Drug Code (NDC) and lists current FDA Authorization (BLA, EUA, Pre-EUA). The only BLA-licensed (FDA-approved) vaccines listed are Pfizer-BioNTech COMIRNATY (in both original and tris-sucrose formulations) for ages 16+ and the Moderna SPIKEVAX (in the original formulation) for ages 18+. All others are listed as either EUA-authorized or Pre-EUA.

13. **With the repeated differentiation by the FDA it seems clear that only Pfizer-**

BioNTech COMIRNATY and Moderna SPIKEVAX are the only BLA-licensed (FDA-approved) COVID-19 vaccines even if there should be no concern regarding safety and efficacy of the EUA-authorized vaccines. As such, they are the only ones which the Secretary of Defense and the Secretary of the Air Force have directed service members to use to comply with their vaccination orders. This differs from the opinion presented in the ASD(HA) memo from 14 Sep 2021 and that memo goes outside the Requirement and Procedures applicable to EUAs outlined in DoDI 6200.02 (reference (n)) Enclosure 3. In the Implementation of EUA (section E.3.3), "DoD Components using medical products under an EUA shall comply with all requirement of section 564 of Reference (d), FDA requirements that are established as a condition of granting the EUA (except as provided in section E3.4 concerning a waiver of an option to refuse), guidance from the Secretary of the Army as Lead Component, and instructions from the ASD(HA)." This would initially indicate that ASD(HA) guidance may be sufficient to allow interchangeability of the BLA-licensed (FDA-approved) and EUA vaccines, but the reference to further guidance related to waiver of an option to refuse points to additional guidance in "Reference (d)", which is Title 21 of the US Code (also referred to as the Federal Food Drug and Cosmetic Act).

14. The relevant portion of the Act is in Section 564 (also known as 21 USC 360bbb-3: Authorization for Medical Products for use in Emergencies) (reference (o)). In 360bbb-3(e) Conditions of Authorization gives the required conditions for use of unapproved (non-BLA-licensed) products indicating that "individuals to whom the product is administered are informed" (section (e)(1)(A)(ii)) "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 (e)(1)(A)(ii)). This points to the fact that United States governmental entities may not compel citizens to take products under Emergency Use Authorization and must notify them of their option to refuse the product. This means the Department of Defense (DoD) and all components of the DoD must give service members the right to refuse EUA vaccines and reveals the reason for the discussion of a waiver of the option to refuse outlined in DoDI 6200.02.

15. E.3.4 of Enclosure 3 of DoDI 6200.02 (reference (n)) outlines the President's ability to waive the option of members of the armed forces to refuse a EUA medical product. It states "In the event that an EUA granted by the Commissioner of Food and Drugs includes a condition that potential recipients are provided an option to refuse administration of the product, **the President may, pursuant to section 1107a of Reference (e), waive the option to refuse for administration of the medical product to members of the armed forces. Such a waiver is allowed if the President determines, in writing, that providing to members of the armed forces an option to refuse is not in the interests of national security.** Only the Secretary of Defense may ask the President to grant a waiver of an option to refuse." Section 1107a of US Code Title 10 (reference (p)), establishes the wavier authority for emergency use products for the president. In 1107a(a) it outlines that "**In the case of the administration of a product authorized for emergency use** under section 564 of the Federal Food, Drug, and Cosmetic Act to members of the armed forces, the condition described in section 564(e)(1)(A)(ii)(III) of such Act and required under paragraph (1)(A) or (2)(A) of such section 564(e), **designed to ensure that individuals are informed of an**

option to accept or refuse administration of a product, may be waived only by the President only if the President determines, in writing, that complying with such requirement is not in the interests of national security."

16. **As none of the vaccine orders from the Secretary of Defense or below has ever made reference to a written Presidential waiver and the orders have repeatedly reiterated mandatory vaccination with "COVID-19 vaccines that receive full licensure from the Food and Drug Administration (FDA)" and the voluntary nature of being immunized with EUA vaccines, I am left to conclude that the President HAS NOT waived the right of members of the armed forces to refuse a EUA vaccine. Additionally, it negates the conclusion of ASD(HA) and the portion of your order which orders me to be vaccinated with anything but the two FDA-approved (BLA-licensed) vaccines, COMIRNATY or SPIKEVAX.**

17. In attempting to comply with receiving COMIRNATY or SPIKEVAX in accordance with the mandatory portion of your order, I began by going to the [redacted] Medical Squadron ([redacted] MDS) on the morning of 15 Mar 2022 where I spoke with one of the enlisted medical technicians in Immunizations. He politely informed me that the [redacted] MDS no longer had vaccines in stock and was now reliant on the Naval Medical Clinic on [redacted] to provide COVID-19 vaccinations. The member did inform me that there were no Pfizer vaccinations available but the clinic would have a Moderna vaccine. I was also informed that if I decided to receive a vaccination from an off-base clinic or pharmacy it would also meet the requirement to be vaccinated.

18. The afternoon of 15 Mar 2022, I went to the Navy Medical Clinic on [redacted] to inquire about the availability of COMRINATY or SPIKEVAX. In talking to the enlisted technician at Immunizations, I learned that they only had the EUA Moderna COVID-19 Vaccine with the Red Label. The acting CIC annotated and signed the attached memorandum (attachment (6)) at my request to provide proof of the clinic's available stock.

19. Following my visit to the Navy Medical clinic I proceeded home and stopped at my local CVS Pharmacy to inquire as to their availability of COMIRNATY or SPIKEVAX. The pharmacy tech was confused by my request for the FDA-approved vaccines and the difference between the EUA and FDA-approved (BLA-licensed) vaccine. After a 3-5 minute discussion with the pharmacy tech, I was finally referred to the pharmacist. Like the tech, the pharmacist was initially confused. After another 5-10 minute discussion the pharmacist came around to the fact that there was only EUA Pfizer-BioNTech COVID-19 Vaccine with the Grey Top and EUA labeling at that pharmacy. The pharmacist was kind enough to fill out a memorandum stating what was available at that pharmacy (attachment (7)).

20. The conversation with the civilian pharmacist and pharmacy tech was a conversation I revisited 14 more times at pharmacies throughout the Fort Worth area on 16 Mar 2022 as I took a vacation day from my civilian job. In each case, the pharmacy techs and pharmacists were confused. Of the 14 locations I visited over approximately 5 hours, 8 were willing to fill out my memorandum stating what was available at their location. **Unfortunately at the locations I was able visit in a reasonable amount of time over two days, none had**

COMIRNATY or SPIKEVAX. I was able to find EUA Pfizer-BioNTech COVID-19 Vaccine with the Purple and Gray Cap, EUA Moderna COVID-19 Vaccine with a Red Cap and EUA Jannsen COVID-19 Vaccine with a Blue Cap.

21. When I asked about the availability of those vaccines many stated they had never heard of them and those at larger pharmacy chains said they didn't show them available within their computer systems. This leads to a larger question about the availability of the FDA-approved (BLA-licensed) COVID-19 vaccines, which may be explained by returning to the CDC IIS Data Code Database website for COVID-Vaccine Related Codes. In the remarks for COMIRNATY and SPIKEVAX the website states that both are "not orderable at this time". This has been consistent for COMIRNATY since I became aware of this website in November of 2021 and I have periodically checked for changes. The only change has been the addition of SPIKEVAX with similar remarks not long after the FDA approval on 31 Jan 2022. The comments also state that Pfizer and Moderna do "not plan to produce any product with these new NDCs and labels over the next few months while EUA authorized product is still available and being made available for U.S. distribution."

22. I am fortunate to have family members in the medical industry so I reached out to one to see if they could confirm the ability to order COMIRNATY and SPIKEVAX by a pharmacist they were friendly with. I gave the link to the CDC IIS Data Code Database website for COVID-Vaccine Related Codes and asked to search for the appropriate NDCs for the two FDA-approved (BLA-licensed) vaccines. The screenshots I received include searches for the NDCs and the brand names COMIRNATY and SPIKEVAX showing that the searches returned zero results for the search terms. This does appear to give credence to the CDC IIS remarks about the vaccines not being orderable.

23. Given all the above, **I have not been able to comply with your order to receive an initial dose of a COVID-19 vaccine with full licensure approval from the FDA AND provide proof by 17 Mar 2022. Additionally, I DO NOT waive my right to refuse to be vaccinated with an EUA COVID-19 vaccine**. I will continue to insist that if I am to be vaccinated in contradiction to my desires as outlined in my Religious Accommodation Request, it will be with one of the fully FDA-approved (BLA-licensed) vaccines, Pfizer-BioNTech COMIRNATY or Moderna SPIKEVAX.

24. Based on the amount of time required to continue to search for those vaccines, I cannot and at this point will not continue to search for the FDA-approved (BLA-licensed) vaccines while not on military status. Additionally, I believe it is no longer my responsibility but the [redacted] Medical Squadron's responsibility to find these vaccines especially given that one of them has been fully approved since 23 Aug 2021. **I request to be granted a 90-day Medical Exemption for Supply (MS) as previously outlined and authorized by AFI 48-110_IP (Section 2-6, subsection a. and appendix C) (reference (a)).**

25. I understand that IAW AFI 48-110 I will have a temporary exemption from vaccinations while my request is being processed. I also understand that I will be counseled by my commander and a military physician regarding: the diseases concerned; specific vaccine

information including product constituents, benefits, and risks; and potential risks of infection incurred by unimmunized individuals. They must determine that I am making an informed decisionand fully understand that my request may have an adverse impact on my deployability, assignment, and/or international travel.

26. If you have any questions, please contact Maj Eric Coulter at [redacted] or [redacted]@us.af.mil.

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ERIC A. COULTER, Maj, USAF
[redacted] Intelligence Officer

7 Attachments:
1. References List, continued
2. PDF printout of FDA Purple Book Search Results for Covid Licensed Biological Products
3. PDF printout of FDA Purple Book Search Results for COMIRNATY
4. PDF printout of FDA Purple Book Search Results for SPIKEVAX
5. PDF printout of CDC IIS Data Code Database for COVID-19 Vaccine Related Codes
6. [redacted] Medical Clinic Acting CIC, *Memorandum on COVID-19 Vaccine Availability*, 15 Mar 2022
7. Collection of 9 Memorandums on COVID-19 Vaccine Availability from Various Pharmacies and Clinics in the Vicinity of [redacted], 15/16 Mar 2022

ATTACHMENT 1

REFERENCES, continued

(e) [redacted] OSS Commander, *Post-RAR Denial Order to Receive Mandatory COVID-19 Vaccine*, 12 Mar 2022

(f) Acting Assistant Secretary of Defense for Health Affairs, *Mandatory Vaccination of Service Members using the Pfizer-BioNTech COVID-19 and COMIRNATY COVID-19 Vaccines Memorandum*, 14 Sep 2021

(g) Department of the Air Force Deputy Director of Staff for COVID-19, *COVID-19 Mandatory Vaccination Implementation Guidance for DAF Service Members*, 14 Mar 2022

(h) Department of the Air Force Deputy Director of Staff for COVID-19, *Deparment of the Air Force Mandatory COVID-19 Mandatory Vaccination Implementation Frequently Asked Questions,* 14 Mar 2022

(i) FDA Biologics License Application (BLA) Approval Letter for Pfizer-BioNTech COMIRNATY, 23 Aug 2021, https://www.fda.gov/media/151710/download

(j) FDA Biologics License Application (BLA) Supplement Approval Letter for Pfizer-BioNTech COMIRNATY, 16 Dec 2021, https://www.fda.gov/media/151710/download

(k) FDA Biologics License Application (BLA) Approval Letter for Moderna SPIKEVAX, 31 Jan 2022, https://www.fda.gov/media/155815/download

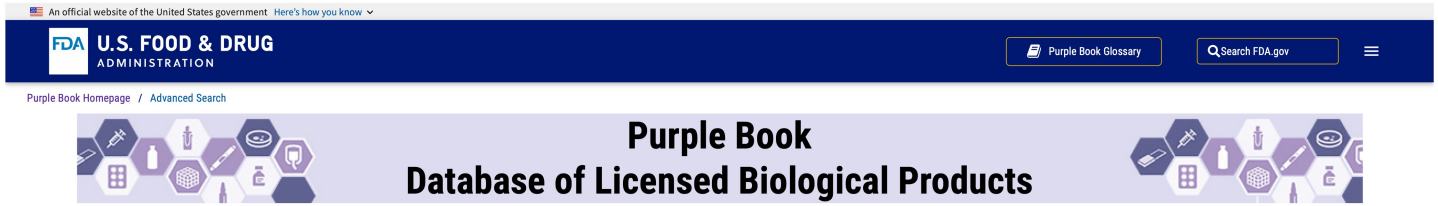
(l) FDA Reissue of Letter of Authorization for Pfizer-BioNTech COVID-19 Vaccine, 3 Jan 2022, https://www.fda.gov/media/150386/download

(m)FDA Reissue of Letter of Authorization for Moderna COVID-19 Vaccine, 15 Mar 2022, FDA Reissue of Letter of Authorization for Pfizer-BioNTech COVID-19 Vaccine, 3 Jan 2022, https://www.fda.gov/media/150386/download

(n) DoD Instruction 6200.02, *Application of Food and Drug Administration (FDA) Rules to Department of Defense Force Health Protection Programs*, 27 Feb 2008

(o) 21 USC, Chapter 9, Subchapter V, Part E, section 360bbb-3, *Authorization for Medical Products for Use in Emergencies*, containing laws in effect on 16 Mar 2022

(p) 10 USC, Subtitle A, Part II, Chapter 55, Section 1107a, *Emergency Use Products*, containing laws in effect on 16 Mar 2022



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Product Label	Applicant	BLA Number	Proprietary Name	Proper Name	License Type	Strength	Licensure	Approval Date
	BioNTech Manufacturing GmbH	125742	Comirnaty	COVID-19 Vaccine, mRNA	351(a)	30UG	Licensed	08/23/2021
	ModernaTX, Inc.	125752	Spikevax	COVID-19 Vaccine, mRNA	351(a)	100UG	Licensed	01/31/2022

Database last updated: March 03, 2022

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Matching card colors indicate a biological product is biosimilar to or interchangeable with a reference product.

Biosimilar(s)

No biosimilar data at this time.

Interchangeable(s)

No interchangeable data at this time.

Reference Product(s)

Proprietary Name
Comirnaty

Proper Name
COVID-19 Vaccine, mRNA

PRODUCT LABEL

Proprietary Name
Spikevax

Proper Name
COVID-19 Vaccine, mRNA

PRODUCT LABEL

To view a list and definitions of Product Presentation icons (e.g., ,), click here. Hover over icons to view additional information.

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Matching card colors indicate a biological product is biosimilar to or interchangeable with a reference product.

Biosimilar(s)

No biosimilar data at this time.

Interchangeable(s)

No interchangeable data at this time.

Reference Product(s)

Proprietary Name
Comirnaty

Proper Name
COVID-19 Vaccine, mRNA

PRODUCT LABEL

Proprietary Name
Spikevax

Proper Name
COVID-19 Vaccine, mRNA

PRODUCT LABEL

To view a list and definitions of Product Presentation icons (e.g., ,), click here. Hover over icons to view additional information.

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Centers for Disease Control and Prevention

COVID-19 Vaccine Related Codes

COVID-19 Vaccine Codes

Preview Posting of COVID-19 Vaccine Codes and Crosswalk for Currently Authorized Vaccines and Anticipation of Potential Vaccine Availability under Emergency Use Authorization (EUA)

Note: Codes will become effective only upon EUA issuance or BLA licensure of COVID-19 vaccine(s) by the Food and Drug Administration (FDA)

The codes and crosswalk for candidate COVID-19 vaccines will be posted for preview in phases as the late-stage clinical trials for candidate vaccines progress. Additional vaccines or codes will be added to this list as they enter late-stage clinical trials or prepare applications for FDA authorization.

The following downloadable table provides a summary of the currently authorized vaccine codes and a preview of the vaccine codes that will be activated if the FDA authorizes use and ACIP votes to recommend the candidate vaccines.

To support this effort, the CDC is working closely with data partners responsible for the creation and distribution of vaccine codes and drug compendia publishers to coordinate the release of codes in advance of potential EUAs to enable systems and users that require these codes to prepare in advance.

The codes for these vaccines are also included in the vaccine code set files unless otherwise noted in the table. Additional code details and fields values are included in the vaccine code sets.

American Medical Association (AMA) COVID-19 CPT® vaccine product and administration codes are now available on the AMA web site. The CPT vaccine product codes are included in the Preview COVID-19 table and the CDC vaccine code sets. You can access further information regarding the COVID-19 CPT codes, as well as the associated coding guidance, using the following link:

https://www.ama-assn.org/practice-management/cpt/covid-19-cpt-vaccine-and-immunization-codes

Download the Preview Table *for US vaccine administration only*: Excel Version

COVID-19 vaccine codes and crosswalks are provided in anticipation of potential vaccine availability under an approved Biologics License Application (BLA), Emergency Use Authorization (EUA), or as a potential vaccine submission for EUA (Pre-EUA) as of 02/14/2022. Codes will become effective for US vaccine administrations only upon EUA issuance and/or BLA approval of COVID-19 vaccine(s) by the FDA. All CVX codes are associated to the new Vaccine Group “COVID-19.” CPT Codes shown are product codes. CPT administrative codes for doses are available on the AMA website. CPT product codes are added as the AMA approves and makes them available.

Manufacturer	FDA Authorization (BLA, EUA, Pre-EUA)	Sale Proprietary Name	Product Description	Unit of Sale NDC10 (UOS)	UoS Package	Unit of Use NDC10 (UOU)	UoU Presentation	CVX Code	CVX Long Description	CVX Short Description

Manufacturer	FDA Authorization (BLA, EUA, Pre-EUA)	Sale Proprietary Name	Product Description	Unit of Sale NDC10 (UOS)	UoS Package	Unit of Use NDC10 (UOU)	UoU Presentation	CVX Code	CVX Long Description	CVX Short Description
Janssen Products, LP	EUA-authorized (18+)	Janssen COVID-19 Vaccine (BLUE CAP)	5×10^10 viral particles/0.5 mL for adult 18+	59676-580-15	CARTON, 10 MULTI-DOSE VIALS	59676-580-05	VIAL, MULTI-DOSE	212	SARS-COV-2 (COVID-19) vaccine, vector non-replicating, recombinant spike protein-Ad26, preservative free, 0.5 mL	COVID-19 vaccine, vector-nr, rS-Ad26, PF, 0.5 mL
Moderna US, Inc.	EUA-authorized (18+)	Moderna COVID-19 Vaccine (RED CAP)	100 mcg/0.5 mL for adult 18+ (existing product)	80777-273-99	CARTON, 10 MULTI-DOSE VIAL 5 mL EACH	80777-273-10	VIAL, 5 mL, MULTI-DOSE VIAL	207	SARS-COV-2 (COVID-19) vaccine, mRNA, spike protein, LNP, preservative free, 100 mcg/0.5mL dose or 50 mcg/0.25mL dose	COVID-19, mRNA, LNP-S, PF, 100 mcg/0.5mL dose or 50 mcg/0.25mL dos
				80777-273-98	CARTON, 10 MULTI-DOSE VIAL 7 mL EACH	80777-273-15	VIAL, 7 mL, MULTI-DOSE VIAL			
Moderna US, Inc.	EUA-authorized (18+)	Moderna COVID-19 Vaccine (RED CAP)	50 mcg/0.25 mL for booster adult 18+ (existing product), drawn from same vial as primary series	80777-273-99	CARTON, 10 MULTI-DOSE VIAL 5 mL EACH	80777-273-10	VIAL, 5 mL, MULTI-DOSE VIAL	207	SARS-COV-2 (COVID-19) vaccine, mRNA, spike protein, LNP, preservative free, 100 mcg/0.5mL dose or 50 mcg/0.25mL dose	COVID-19, mRNA, LNP-S, PF, 100 mcg/0.5mL dose or 50 mcg/0.25mL dos
				80777-273-98	CARTON, 10 MULTI-DOSE VIAL 7 mL EACH	80777-273-15	VIAL, 7 mL, MULTI-DOSE VIAL			

Moderna US, Inc. Manufacturer	PDA EUA Authorization (BLA, EUA, Pre-EUA)	Moderna COVID-19 Vaccine Proprietary Name (DARK BLUE CAP)	50 mcg/0.50 mL for adult Product Description, concentration	80777-273-99 NDC10 (UOS)	CARTON, 10 VIAL 2.5 mL EACH	80777-055-05 NDC10 (UOU)	VIAL, 2.5 mL, MULTI-DOSE VIAL Presentation	221 CVX Code	SARS-COV-2 (COVID-19) vaccine, mRNA, spike protein, LNP, preservative free, 50 mcg/0.5 mL dose	COVID-19, mRNA, LNP-S, PF, 50 mcg/0.5 mL dose Description
Pfizer-BioNTech	EUA-authorized for ages 12 yrs +	Pfizer-BioNTech COVID-19 Vaccine (PURPLE CAP) (Original product formulation)	30 mcg/0.3 mL for primary series, IC 3rd dose, booster	59267-1000-2	CARTON, 195 MULTI-DOSE VIALS	59267-1000-1	MULTI-DOSE VIAL	208	SARS-COV-2 (COVID-19) vaccine, mRNA, spike protein, LNP, preservative free, 30 mcg/0.3 mL dose	COVID-19, mRNA, LNP-S, PF, 30 mcg/0.3 mL dose
				59267-1000-3	CARTON, 25 MULTI-DOSE VIALS					
Pfizer-BioNTech	EUA-authorized for ages 12 yrs + Note: BLA-licensed for (16+)	Pfizer-BioNTech COVID-19 Vaccine (GRAY CAP) (Tris-sucrose formulation)	30 mcg/0.3 mL for primary series, IC 3rd dose, booster	59267-1025-3	CARTON, 25 MULTI-DOSE VIALS	59267-1025-1	VIAL, 2.25 mL, MULTI-DOSE VIAL	217	SARS-COV-2 (COVID-19) vaccine, mRNA, spike protein, LNP, preservative free, 30 mcg/0.3 mL dose	COVID-19, mRNA, LNP-S, PF, 30 mcg/0.3 mL dose
				59267-1025-4	CARTON, 10 MULTI-DOSE VIALS					
Pfizer-BioNTech	EUA-authorized for ages 5 yrs to < 12 yrs	Pfizer-BioNTech COVID-19 Vaccine (ORANGE CAP) (Tris-sucrose	10 mcg/0.2 mL for primary series, IC 3rd dose	59267-1055-4	CARTON, 10 MULTI-DOSE VIALS	59267-1055-1	VIAL, 2 mL, MULTI-DOSE VIAL	218	SARS-COV-2 (COVID-19) vaccine, mRNA, spike protein, LNP, preservative free, 10 mcg/0.2 mL dose, tris-sucrose formulation	COVID-19, mRNA, LNP-S, PF, 10 mcg/0.2 mL dose, tris-sucrose

Manufacturer	FDA Authorization (BLA, EUA, Pre-EUA)	formulation) Sale Proprietary Name	Product Description	Unit of Sale NDC10 (UOS)	UoS Package	Unit of Use NDC10 (UOU)	UoU Presentation	CVX Code	CVX Long Description	CVX Short Description
Pfizer-BioNTech	Pre-EUA for ages 6 mo to <5 yrs	Pfizer-BioNTech COVID-19 Vaccine (MAROON CAP) (Tris-sucrose formulation)	3 mcg/0.2 mL for primary series	59267-0078-4	CARTON, 10 MULTI-DOSE VIALS	59267-0078-1	VIAL, 2 mL, MULTI-DOSE VIAL	219	SARS-COV-2 (COVID-19) vaccine, mRNA, spike protein, LNP, preservative free, 3 mcg/0.2 mL dose, tris-sucrose formulation	COVID-19, mRNA, LNP-S, PF, 3 mcg/0.2 mL dose, tris-sucrose
Novavax, Inc.	Pre-EUA	Novavax COVID-19 Vaccine	5 mcg/0.5 mL, primary series, adult	80631-100-10	CARTON, 10 VIAL, MULTI-DOSE	80631-100-01	VIAL, MULTI-DOSE, 5 mL	211	SARS-COV-2 (COVID-19) vaccine, Subunit, recombinant spike protein-nanoparticle+Matrix-M1 Adjuvant, preservative free, 0.5mL per dose	COVID-19 vaccine, Subunit, rS-nanoparticle+Matrix-M1 Adjuvant, PF, 0.5 mL
Sanofi Pasteur	Pre-EUA Authorization	Sanofi Pasteur COVID-19 Vaccine, primary series, adult	10mcg/0.5mL dose, including added AS03 adjuvant, primary series	No production planned for adult series vaccine in U.S. market at this time				226	SARS-COV-2 (COVID-19) vaccine, D614, recomb, preS dTM, AS03 adjuvant added, preservative free, 10mcg/0.5mL dose	COVID-19, D614, recomb, preS dTM, AS03 adjuvant add, PF, 10mcg/0.5mL

Manufacturer	FDA Authorization (BLA, EUA, Pre-EUA)	Sale Proprietary Name	Product Description	Unit of Sale NDC10 (UOS)	UoS Package	Unit of Use NDC10 (UOU)	UoU Presentation	CVX Code	CVX Long Description	CVX Short Description
Sanofi Pasteur	Pre-EUA	Sanofi Pasteur COVID-19 Vaccine	5mcg/0.5mL dose, recombinant protein subunit, booster dose, adult	49281-558-20	10 MULTI-DOSE VIALS	49281-558-78	VIAL, MULTI-DOSE, ANTIGEN ONLY	225	SARS-COV-2 (COVID-19) vaccine, D614, CoV using spike protein recombinant protein subunit (CoV2 preS dTM), AS03 adjuvant added, preservative free, 5mcg/0.5mL dose	COVID-19, D614, recomb, preS dTM, AS03 adjuvant add, PF, 5mcg/0.5mL
AstraZeneca Pharmaceuticals LP	Pre-EUA	AstraZeneca COVID-19 Vaccine	5×10^10 viral particles/0.5 mL, adult	No active NDC codes for U.S. Market				210	SARS-COV-2 (COVID-19) vaccine, vector non-replicating, recombinant spike protein-ChAdOx1, preservative free, 0.5 mL	COVID-19 vaccine, vector-nr, rS-ChAdOx1, PF, 0.5 m

Unspecified US COVID-19 Vaccine CVX Code

CVX Short Description	CVX Code	CVX Long Description	Note	Vaccine Status
SARS-COV-2 (COVID-19) vaccine, UNSPECIFIED	213	SARS-COV-2 (COVID-19) vaccine, UNSPECIFIED	Unspecified code for COVID-19 not to be used to record patient US administration. May be used to record historic US administration if product is not known. CVX code 500 should be used to record Non-US vaccine where product is not known.	Inactive

The following vaccines and associated tradenames have been approved by the FDA under BLA License. They are listed separately because while they may represent the same formulations as the EUA authorized and labeled products listed above, the NDCs listed with the new BLA licensed tradenames in the FDA BLA approval or the FDA Structured Product Labels (SPL) are not currently being produced by the manufacturers while EUA product is available.

Manufacturer	FDA Authorization (BLA, EUA, Pre-EUA)	Sale Proprietary Name	Product Description	Unit of Sale NDC10 (UOS)	UoS Package	Unit of Use NDC10 (UOU)	UoU Presentation	
Pfizer-BioNTech	BLA-licensed for ages 16+	COMIRNATY	30 mcg/0.3 mL for adult 16+ (original formula)	0069-1000-02	CARTON, 195 MULTI-DOSE VIALS	0069-1000-01	VIAL, 2 mL, MULTI-DOSE VIAL	COMINARTY products are not orderable at this time. NDCs are listed per FDA Structured Product Label (SPL) document for the BLA licensed product. These codes are not included in CDC Vaccine Code Set files at this time. Pfizer has provided the following statement regarding the COMINARTY branded NDCs and labels: "Pfizer received FDA BLA license on 8/23/2021 for its COVID-19 vaccine for use in individuals 16 and older (COMIRNATY). At that time, the FDA published a BLA package insert that included the approved new COVID-19 vaccine tradename
				00069-1000-03	CARTON, 25 MULTI-DOSE VIALS			
Pfizer-BioNTech	BLA-licensed for ages 16+	COMIRNATY	30 mcg/0.3 mL for adult 16+ (Same as EUA tris sucrose formula)	0069-2025-10	CARTON, 10 MULTI-DOSE VIALS	0069-2025-01	VIAL, 2 mL, MULTI-DOSE VIAL	

Manufacturer	FDA Authorization (BLA, EUA, Pre-EUA)	Sale Proprietary Name	Product Description	Unit of Sale NDC10 (UOS)	UoS Package	Unit of Use NDC10 (UOU)	UoU Presentation	
				0069-2025-25	CARTON, 25 MULTI-DOSE VIALS			COMIRNATY and listed 2 new NDCs (0069-1000-03, 0069-1000-02) and images of labels with the new tradename. Pfizer subsequently received approval to amend its FDA BLA License on December 16, 2021 to include its tris-sucrose formulation COVID-19 vaccine for use in individuals 16 and older (COMIRNATY). At that time, the FDA published a BLA package insert that included the approved new COVID-19 vaccine tradename COMIRNATY and listed 3 new NDCs (0069-2025-10, 0069-2025-25, 0069-2025-01) and images of labels with the new tradename. At present, Pfizer does not plan to produce any product with these new NDCs and labels over the next few months while EUA authorized product is still available and being made available for U.S. distribution. As such, the CDC, AMA, and drug compendia may not publish these new codes until Pfizer has determined when the product will be produced with the BLA labels."
Moderna US, Inc.	BLA-licensed for ages 18+	SPIKEVAX	0.5 mL dose (same as original EUA formula)	80777-100-99	CARTON, 10 MULTI-DOSE VIALS, EACH VIAL CONTAINING 5.5 mL	NA	VIAL, 5.5 mL, MULTI-DOSE VIAL	SPIKEVAX products are not orderable at this time. NDCs are listed per FDA Structured Product Label (SPL) document for the BLA licensed product. These codes are not included in CDC Vaccine Code Set files at this time. Moderna has provided the following statement regarding the SPIKEVAX branded NDCs and labels: "Moderna received FDA BLA license on January 31, 2022, for its COVID-19 vaccine SPIKEVAX (COVID-19 Vaccine, mRNA) for use in individuals 18 and older. At that time, the FDA published a BLA package insert that included the new approved trade name SPIKEVAX and listed 2 new NDCs (80777-100-99, 80777-100-98). At present, Moderna does not plan to produce any product with these new NDCs and labels over the next few months while EUA authorized Moderna COVID-19 Vaccine product is still available and being made available for U.S. distribution. As such, the CDC, AMA, and drug compendia may delay publishing these new codes until Moderna has determined when the product will be produced with the BLA labels."
				80777-100-98	CARTON, 10 MULTI-DOSE VIALS, EACH VIAL CONTAINING 7.5 mL	NA	VIAL, 7.5 mL, MULTI-DOSE VIAL	

Download the Preview Table *for Non-US vaccine administration only*: Excel Version

Preview Posting of COVID-19 Vaccine Codes and Crosswalks to be used for Non-US vaccine administration. All COVID-19 related CVX codes are associated to the Vaccine Group "COVID-19". Data as of 11/15/2021. CVX and MVX codes are identified for vaccines that have received emergency authorization from the World Health Organization (WHO), US Food and Drug Administration (FDA) or both. CVX codes have also been added without associated MVX for vaccines that are manufactured and administered outside the US but which have not been authorized by the WHO. The list of vaccines not authorized by the WHO may be incomplete. The list of vaccines indicated to be WHO-authorized will be updated periodically as the CDC monitors WHO published information.

CVX Code	CVX Long Description	CVX Short Description	CVX Note	CVX Status	MVX Code	MVX Manufacturer	Product Tradename(s)

CVX Code	CVX Long Description	CVX Short Description	CVX Note	CVX Status	MVX Code	MVX Manufacturer	Product Tradename(s)
207	SARS-COV-2 (COVID-19) vaccine, mRNA, spike protein, LNP, preservative free, 100 mcg or 50 mcg dose	COVID-19, mRNA, LNP-S, PF, 100 mcg or 50 mcg dose	EUA 12/18/2020, 2-dose vaccine. Used to record Moderna vaccines administered in the US and in non-US locations (includes tradename Spikevax)	Active	MOD	Moderna US, Inc.	Moderna COVID-19 Vaccine (non-US Spikevax)
208	SARS-COV-2 (COVID-19) vaccine, mRNA, spike protein, LNP, preservative free, 30 mcg/0.3mL dose	COVID-19, mRNA, LNP-S, PF, 30 mcg/0.3 mL dose	EUA 12/11/2020, 2-dose vaccine. Used to record Pfizer vaccines administered in the US and in non-US locations (includes tradename Comirnaty)	Active	PFR	Pfizer, Inc	Pfizer-BioNTech COVID-19 Vaccine (US-EUA), COMIRNATY (US-BLA), COMIRNATY (Non-US)
210	SARS-COV-2 (COVID-19) vaccine, vector non-replicating, recombinant spike protein-ChAdOx1, preservative free, 0.5 mL	COVID-19 vaccine, vector-nr, rS-ChAdOx1, PF, 0.5 mL	Potential EUA, 2-dose vaccine. AstraZeneca vaccine is authorized by the WHO and recognized towards immunity in the US. Non-US WHO authorized tradenames/identifiers include VAXZEVRIA, AZD1222, ChAdOx1 nCoV-19, COVISHIELD	Non-US	ASZ	AstraZeneca	AstraZeneca COVID-19 Vaccine (Non-US tradenames include VAXZEVRIA, COVISHIELD)
212	SARS-COV-2 (COVID-19) vaccine, vector non-replicating, recombinant spike protein-Ad26, preservative free, 0.5 mL	COVID-19 vaccine, vector-nr, rS-Ad26, PF, 0.5 mL	EUA 02/27/2021, 1-dose vaccine. Used to record Janssen/J&J vaccines administered in the US and in non-US locations	Active	JSN	Janssen	Janssen (J&J) COVID-19 Vaccine
510	SARS-COV-2 COVID-19 Inactivated Virus Non-US Vaccine Product (BIBP, Sinopharm)	COVID-19 IV Non-US Vaccine (BIBP, Sinopharm)	WHO authorized pandemic vaccine. Recognized towards immunity in US	Non-US	SPH	Sinopharm-Biotech	Sinopharm (BIBP) COVID-19 Vaccine
511	SARS-COV-2 COVID-19 Inactivated Virus Non-US Vaccine Product (CoronaVac, Sinovac)	COVID-19 IV Non-US Vaccine (CoronaVac, Sinovac)	WHO authorized pandemic vaccine. Recognized towards immunity in US	Non-US	SNV	Sinovac	Coronavac (Sinovac) COVID-19 Vaccine
500	SARS-COV-2 COVID-19 Non-US Vaccine, Specific Product Unknown	COVID-19 Non-US Vaccine, Product Unknown	Pandemic Non-US Covid Administration – specific CVX or product unknown	Non-US			
501	SARS-COV-2 COVID-19 Inactivated Virus Non-US Vaccine Product (QAZCOVID-IN)	COVID-19 IV Non-US Vaccine (QAZCOVID-IN)	Pandemic Non-US Vaccine not Authorized by WHO – not counted toward immunity in US	Non-US			
502	SARS-COV-2 COVID-19 Inactivated Virus Non-US Vaccine Product (COVAXIN)	COVID-19 IV Non-US Vaccine (COVAXIN)	Pandemic Non-US Vaccine Authorized by WHO 11-3-2021, recognized toward immunity in US, https://extranet.who.int/pqweb/vaccines/who-recommendation-bharat-biotech-international-ltd-covid-19-vaccine-whole-virion	Non-US	BBI	Bharat Biotech International Limited	COVAXIN (Bharat) COVID-19 Vaccine
503	SARS-COV-2 COVID-19 Live Attenuated Virus Non-US Vaccine Product (COVIVAC)	COVID-19 LAV Non-US Vaccine (COVIVAC)	Pandemic Non-US Vaccine not Authorized by WHO – not counted toward immunity in US	Non-US			
504	SARS-COV-2 COVID-19 Viral Vector Non-replicating Non-US Vaccine Product (Sputnik Light)	COVID-19 VVnr Non-US Vaccine (Sputnik Light)	Pandemic Non-US Vaccine not Authorized by WHO – not counted toward immunity in US	Non-US			
505	SARS-COV-2 COVID-19 Viral Vector Non-replicating Non-US Vaccine Product (Sputnik V)	COVID-19 VVnr Non-US Vaccine (Sputnik V)	Pandemic Non-US Vaccine not Authorized by WHO – not counted toward immunity in US	Non-US			

CVX Code	CVX Long Description	CVX Short Description	CVX Note	CVX Status	MVX Code	MVX Manufacturer	Product Tradename(s)
506	SARS-COV-2 COVID-19 Viral Vector Non-replicating Non-US Vaccine Product (CanSino Biological Inc./Beijing Institute of Biotechnology)	COVID-19 VVnr Non-US Vaccine (CanSino Biological Inc./Beijing Institute of Biotechnology)	Pandemic Non-US Vaccine not Authorized by WHO – not counted toward immunity in US	Non-US			
507	SARS-COV-2 COVID-19 Protein Subunit Non-US Vaccine Product (Anhui Zhifei Longcom Biopharmaceutical + Institute of Microbiology, Chinese Academy of Sciences)	COVID-19 PS Non-US Vaccine (Anhui Zhifei Longcom Biopharmaceutical + Institute of Microbiology, Chinese Academy of Sciences)	Pandemic Non-US Vaccine not Authorized by WHO – not counted toward immunity in US	Non-US			
508	SARS-COV-2 COVID-19 Protein Subunit Non-US Vaccine Product (Jiangsu Province Centers for Disease Control and Prevention)	COVID-19 PS Non-US Vaccine (Jiangsu Province Centers for Disease Control and Prevention)	Pandemic Non-US Vaccine not Authorized by WHO – not counted toward immunity in US	Non-US			
509	SARS-COV-2 COVID-19 Protein Subunit Non-US Vaccine Product (EpiVacCorona)	COVID-19 PS Non-US Vaccine (EpiVacCorona)	Pandemic Non-US Vaccine not Authorized by WHO – not counted toward immunity in US	Non-US			

COVID-19 Emergency Use Authorization Recipient and Caregiver Fact Sheets

Preview Posting of Codes for Emergency Use Authorization (EUA) Fact Sheets for Recipients and Caregivers

Vaccine information statements (VISs), used only for licensed vaccines, will not be available for COVID-19 vaccines while they are under Emergency Use Authorization (EUA). For vaccines under an EUA, the FDA requires a vaccine-specific Fact Sheet for Recipients and Caregivers be provided to vaccine recipients or their caregivers.

The COVID-19 vaccine-related codes are provided in anticipation of potential vaccine availability under an EUA. If a vaccine is not authorized, the code will be retired.

The FDA issued Emergency Use Authorization for the Moderna COVID-19 vaccine on Friday December 18, 2020. Information regarding that vaccine as well as both the EUA Provider Fact Sheet and the EUA Recipient and Caregiver Fact Sheets is now available on the following FDA web site link:

https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine

The FDA issued Emergency Use Authorization for the Pfizer BioNTech COVID-19 vaccine on Friday December 11, 2020. Information regarding that vaccine as well as both the EUA Provider Fact Sheet and the EUA Recipient and Caregiver Fact Sheets is now available on the following FDA web site link:

https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine

The FDA issued Emergency Use Authorization for the Janssen (Johnson & Johnson) COVID-19 vaccine on Saturday

February 27, 2021. Information regarding that vaccine as well as both the EUA Provider Fact Sheet and the EUA Recipient and Caregiver Fact Sheets is now available on the following FDA web site link:

https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine

The following downloadable VIS code files will include the new EUA Fact Sheet for Recipients records:

- Excel version of table

CVX Code	EUA Recipient/Caregiver Fact Sheet Description	Document Barcode String	Edition Date	Edition Status	HTML URL	PDF URL
207	COVID-19 Moderna Vaccine EUA Recipient-Caregiver Fact Sheet	25308869830003491121060 1	1/31/2022	Current	https://www.cdc.gov/vaccines/covid-19/eua/modernatx.html	https://www.cdc.gov/vaccines/covid-19/eua/modernatx.pdf
208, 217	COVID-19 Pfizer BioNTech EUA Recipient-Caregiver Fact Sheet – 12 years and older	25308869830003321121050 1	1/31/2022	Current	https://www.cdc.gov/vaccines/covid-19/eua/pfizer.html	https://www.cdc.gov/vaccines/covid-19/eua/pfizer.pdf
218	COVID-19 Pfizer BioNTech EUA Recipient-Caregiver Fact Sheet – Pediatric 5 – 11 years	25308869830004241121100 1	1/3/2022	Current	https://www.cdc.gov/vaccines/covid-19/eua/pfizer-children.html	https://www.cdc.gov/vaccines/covid-19/eua/pfizer-children.pdf
219	COVID-19 Pfizer BioNTech EUA Recipient-Caregiver Fact Sheet-Pediatric <5 yrs	25308869830004861122010 1	3/1/2022	Current	https://www.cdc.gov/vaccines/covid-19/eua/pfizer-children-under-5-years.html	https://www.cdc.gov/vaccines/covid-19/eua/pfizer-children-under-5-years.pdf
212	COVID-19 Janssen Vaccine EUA Recipient-Caregiver Fact Sheet	25308869830003631121020 1	1/31/2022	Current	https://www.cdc.gov/vaccines/covid-19/eua/janssen.html	https://www.cdc.gov/vaccines/covid-19/eua/janssen.pdf

*Edition Date represents the date of update printed on the actual fact sheet document published by the FDA. It may not be the same as the EUA authorization date or the date embedded in the Document Barcode String.

Page last reviewed: March 15, 2022

DEPARTMENT OF THE AIR FORCE
AIR FORCE RESERVE COMMAND

15 MAR 22
Date

MEMORANDUM FOR RECORD

FROM: LCDR [redacted]
(Name and Rank)

SUBJECT: COVID-19 Vaccine Availability

1. [redacted] (Unit or Clinic Name) currently have the following COVID-19 vaccines available for administration to military service members (check all that apply):

- ☐ Pfizer-BioNTech COMIRNATY (original formula) – BLA-licensed for ages 16+
- ☐ Pfizer-BioNTech COMIRNATY (tris-sucrose formula) – BLA-licensed for ages 16+
- ☐ Pfizer-BioNTech COVID-19 Vaccine Purple Cap (original formula) – EUA authorized for ages 12+
- ☐ Pfizer-BioNTech COVID-19 Vaccine Gray Cap (tris-sucrose formula) – EUA authorized for ages 12+
- ☐ Moderna SPIKEVAX – BLA-licensed for ages 18+
- ☑ Moderna COVID-19 Vaccine Red Cap – EUA authorized for ages 18+
- ☐ Janssen COVID-19 Vaccine Blue Cap – EUA authorized for ages 18+

2. For the vaccines which are currently unavailable, the expected in-stock date is (write date of expected resupply):

i. Pfizer-BioNTech COMIRNATY _____
ii. Pfizer-BioNTech COMIRNATY _____
iii. Pfizer-BioNTech COVID-19 Vaccine Purple Cap _____
iv. Pfizer-BioNTech COVID-19 Vaccine Gray Cap _____
v. Moderna SPIKEVAX _____
vi. Moderna COVID-19 Vaccine Red Cap _____
vii. Janssen COVID-19 Vaccine Blue Cap _____

3. If you have any questions, please contact me at [redacted] (phone number) or [redacted].MIL@MAIL.MIL (email).

[redacted], LCDR, OIC (ACTING)
(Name, Rank, Position and Unit)

FROM BENBROOK CVS
8660 BENBROOK HWY
(817)249-4040

3/15/22
Date

MEMORANDUM FOR RECORD

FROM: [redacted] RPh.
(Name and Position)

SUBJECT: COVID-19 Vaccine Availability

1. CVS Benbrook (Unit or Clinic Name) currently have the following COVID-19 vaccines available for administration to military service members (check all that apply):

- ☐ Pfizer-BioNTech COMIRNATY (original formula) – BLA-licensed for ages 16+
- ☐ Pfizer-BioNTech COMIRNATY (tris-sucrose formula) – BLA-licensed for ages 16+
- ☐ Pfizer-BioNTech COVID-19 Vaccine Purple Cap (original formula) – EUA authorized for ages 12+
- ☑ Pfizer-BioNTech COVID-19 Vaccine Gray Cap (tris-sucrose formula) – EUA authorized for ages 12+
- ☐ Moderna SPIKEVAX – BLA-licensed for ages 18+
- ☐ Moderna COVID-19 Vaccine Red Cap – EUA authorized for ages 18+
- ☐ Janssen COVID-19 Vaccine Blue Cap – EUA authorized for ages 18+

2. For the vaccines which are currently unavailable, the expected in-stock date is (write date of expected resupply):

i. Pfizer-BioNTech COMIRNATY _____
ii. Pfizer-BioNTech COMIRNATY _____
iii. Pfizer-BioNTech COVID-19 Vaccine Purple Cap _____
iv. Pfizer-BioNTech COVID-19 Vaccine Gray Cap _____
v. Moderna SPIKEVAX _____
vi. Moderna COVID-19 Vaccine Red Cap _____
vii. Janssen COVID-19 Vaccine Blue Cap _____

3. If you have any questions, please contact me at _____ (phone number) or _____ (email).

[redacted] RPh [redacted]
(Name, Position and License #)

FROM WALGREENS 6593
8651 BENBROOK BLVD.
(817) 249-5434

3.16.22
Date

MEMORANDUM FOR RECORD

FROM: _____
(Name and Position)

SUBJECT: COVID-19 Vaccine Availability

1. [redacted] RPh (Unit or Clinic Name) currently have the following COVID-19 vaccines available for administration to military service members (check all that apply):

- ☐ Pfizer-BioNTech COMIRNATY (original formula) – BLA-licensed for ages 16+
- ☐ Pfizer-BioNTech COMIRNATY (tris-sucrose formula) – BLA-licensed for ages 16+
- ☐ Pfizer-BioNTech COVID-19 Vaccine Purple Cap (original formula) – EUA authorized for ages 12+
- ☑ Pfizer-BioNTech COVID-19 Vaccine Gray Cap (tris-sucrose formula) – EUA authorized for ages 12+
- ☐ Moderna SPIKEVAX – BLA-licensed for ages 18+
- ☐ Moderna COVID-19 Vaccine Red Cap – EUA authorized for ages 18+
- ☐ Janssen COVID-19 Vaccine Blue Cap – EUA authorized for ages 18+

2. For the vaccines which are currently unavailable, the expected in-stock date is (write date of expected resupply):

i. Pfizer-BioNTech COMIRNATY _____
ii. Pfizer-BioNTech COMIRNATY _____
iii. Pfizer-BioNTech COVID-19 Vaccine Purple Cap _____
iv. Pfizer-BioNTech COVID-19 Vaccine Gray Cap _____
v. Moderna SPIKEVAX _____
vi. Moderna COVID-19 Vaccine Red Cap _____
vii. Janssen COVID-19 Vaccine Blue Cap _____

3. If you have any questions, please contact me at 817.249.5434 (phone number) or [redacted]@store.walgreens.com (email).

[redacted], RPh
(Name, Position and License #)

Walgreens #6593
8651 Benbrook Hwy.
Benbrook, TX 76126

FROM PERRONE PHARMACY
3921 Hwy 377 SOUTH
(817) 738-2135

3/16/22
Date

MEMORANDUM FOR RECORD

FROM: _____
(Name and Position)

SUBJECT: COVID-19 Vaccine Availability

1. [redacted] Perrone Pharmacy (Unit or Clinic Name) currently have the following COVID-19 vaccines available for administration to military service members (check all that apply):

- ☐ Pfizer-BioNTech COMIRNATY (original formula) – BLA-licensed for ages 16+
- ☐ Pfizer-BioNTech COMIRNATY (tris-sucrose formula) – BLA-licensed for ages 16+
- ☑ Pfizer-BioNTech COVID-19 Vaccine Purple Cap (original formula) – EUA authorized for ages 12+
- ☐ Pfizer-BioNTech COVID-19 Vaccine Gray Cap (tris-sucrose formula) – EUA authorized for ages 12+
- ☐ Moderna SPIKEVAX – BLA-licensed for ages 18+
- ☑ Moderna COVID-19 Vaccine Red Cap – EUA authorized for ages 18+
- ☐ Janssen COVID-19 Vaccine Blue Cap – EUA authorized for ages 18+

2. For the vaccines which are currently unavailable, the expected in-stock date is (write date of expected resupply):

i. Pfizer-BioNTech COMIRNATY _____
ii. Pfizer-BioNTech COMIRNATY _____
iii. Pfizer-BioNTech COVID-19 Vaccine Purple Cap _____
iv. Pfizer-BioNTech COVID-19 Vaccine Gray Cap _____
v. Moderna SPIKEVAX _____
vi. Moderna COVID-19 Vaccine Red Cap _____
vii. Janssen COVID-19 Vaccine Blue Cap _____

3. If you have any questions, please contact me at _____ (phone number) or _____ (email).

[redacted]
(Name, Position and License #)
Pharmacist [redacted] TX

FROM CVS 38223
3614 CAMP BOWIE BLVD
(817) 870-1873

03/16/22
Date

MEMORANDUM FOR RECORD

FROM: [redacted] - PHARMACIST
(Name and Position)

SUBJECT: COVID-19 Vaccine Availability

1. CVS PHARMACY #7237 (Clinic Name) currently has the following COVID-19 vaccines available for administration (check all that apply):

- ☐ Pfizer-BioNTech COMIRNATY (original formula) – BLA-licensed for ages 16+
- ☐ Pfizer-BioNTech COMIRNATY (tris-sucrose formula) – BLA-licensed for ages 16+
- ☐ Pfizer-BioNTech COVID-19 Vaccine Purple Cap (original formula) – EUA authorized for ages 12+
- ☑ Pfizer-BioNTech COVID-19 Vaccine Gray Cap (tris-sucrose formula) – EUA authorized for ages 12+
- ☐ Moderna SPIKEVAX – BLA-licensed for ages 18+
- ☐ Moderna COVID-19 Vaccine Red Cap – EUA authorized for ages 18+
- ☐ Janssen COVID-19 Vaccine Blue Cap – EUA authorized for ages 18+

2. If you have any questions, please contact me at 817-870-1873 (phone number) or _____ (email).

[redacted]
(Name, Position and License #)
PHARMACIST
LICENSE # [redacted]

FROM WALGREENS 9763
4515 CAMP BOWIE
(817) 735-8185

03/16/2022
Date

MEMORANDUM FOR RECORD

FROM: [redacted] RPh
(Name and Position)

SUBJECT: COVID-19 Vaccine Availability

1. Walgreens Store #9763 (Clinic Name) currently has the following COVID-19 vaccines available for administration (check all that apply):

- ☐ Pfizer-BioNTech COMIRNATY (original formula) – BLA-licensed for ages 16+
- ☐ Pfizer-BioNTech COMIRNATY (tris-sucrose formula) – BLA-licensed for ages 16+
- ☐ Pfizer-BioNTech COVID-19 Vaccine Purple Cap (original formula) – EUA authorized for ages 12+
- ☑ Pfizer-BioNTech COVID-19 Vaccine Gray Cap (tris-sucrose formula) – EUA authorized for ages 12+ → Currently Available
- ☐ Moderna SPIKEVAX – BLA-licensed for ages 18+
- ☐ Moderna COVID-19 Vaccine Red Cap – EUA authorized for ages 18+
- ☐ Janssen COVID-19 Vaccine Blue Cap – EUA authorized for ages 18+

2. If you have any questions, please contact me at 817-735 8185 (phone number) or _____ (email).

Walgreens #09763
4515 Camp Bowie
Fort Worth, TX 76107
(817) 735-8185
RPh
(Name, Position and License #)

BEST VALUE RIDGLEA
DRUG – CAMP BOWIE
16 MAR 2022
[redacted]

Date

MEMORANDUM FOR RECORD

FROM: _____
(Name and Position)

SUBJECT: COVID-19 Vaccine Availability

1. _____ (Clinic Name) currently has the following COVID-19 vaccines available for administration (check all that apply):

- ☐ Pfizer-BioNTech COMIRNATY (original formula) – BLA-licensed for ages 16+
- ☐ Pfizer-BioNTech COMIRNATY (tris-sucrose formula) – BLA-licensed for ages 16+
- ☐ Pfizer-BioNTech COVID-19 Vaccine Purple Cap (original formula) – EUA authorized for ages 12+
- ☐ Pfizer-BioNTech COVID-19 Vaccine Gray Cap (tris-sucrose formula) – EUA authorized for ages 12+
- ☐ Moderna SPIKEVAX – BLA-licensed for ages 18+
- √ ☐ Moderna COVID-19 Vaccine Red Cap – EUA authorized for ages 18+
- ☐ Janssen COVID-19 Vaccine Blue Cap – EUA authorized for ages 18+

2. If you have any questions, please contact me at _____ (phone number) or _____ (email).

_____
(Name, Position and License #)

√ – only vaccine available to us at this time.

[redacted] RPh

[redacted] PharmD

Ridglea Drug

817-737-66655

FROM NORTHSTAR PHARMACY
6014 SW BLVD FRONTAGE RD.
(469) 296-8132

3/16/22
Date

MEMORANDUM FOR RECORD

FROM: [redacted] PIC
(Name and Position)

SUBJECT: COVID-19 Vaccine Availability

1. Northstar Pharmacy. (Clinic Name) currently has the following COVID-19 vaccines available for administration (check all that apply):

- ☐ Pfizer-BioNTech COMIRNATY (original formula) – BLA-licensed for ages 16+
- ☐ Pfizer-BioNTech COMIRNATY (tris-sucrose formula) – BLA-licensed for ages 16+
- ☐ Pfizer-BioNTech COVID-19 Vaccine Purple Cap (original formula) – EUA authorized for ages 12+
- ☑ Pfizer-BioNTech COVID-19 Vaccine Gray Cap (tris-sucrose formula) – EUA authorized for ages 12+
- ☐ Moderna SPIKEVAX – BLA-licensed for ages 18+
- ☑ Moderna COVID-19 Vaccine Red Cap – EUA authorized for ages 18+
- ☑ Janssen COVID-19 Vaccine Blue Cap – EUA authorized for ages 18+

2. If you have any questions, please contact me at 469-296-8132 (phone number) or [redacted]@gmail.com (email).

[redacted] PIC
(Name, Position and License #)

FROM CVS 7801
6000 BRYANT IRVIN RD
(817) 292-8000

3/16/22
Date

MEMORANDUM FOR RECORD

FROM: [redacted] Pharmacist
(Name and Position)

SUBJECT: COVID-19 Vaccine Availability

1. CVS — 7801 (Clinic Name) currently has the following COVID-19 vaccines available for administration (check all that apply):

- ☐ Pfizer-BioNTech COMIRNATY (original formula) – BLA-licensed for ages 16+
- ☐ Pfizer-BioNTech COMIRNATY (tris-sucrose formula) – BLA-licensed for ages 16+
- ☐ Pfizer-BioNTech COVID-19 Vaccine Purple Cap (original formula) – EUA authorized for ages 12+
- ☑ Pfizer-BioNTech COVID-19 Vaccine Gray Cap (tris-sucrose formula) – EUA authorized for ages 12+
- ☐ Moderna SPIKEVAX – BLA-licensed for ages 18+
- ☐ Moderna COVID-19 Vaccine Red Cap – EUA authorized for ages 18+
- ☐ Janssen COVID-19 Vaccine Blue Cap – EUA authorized for ages 18+

2. If you have any questions, please contact me at 817 292 8000 (phone number) or _____ (email).

_____
(Name, Position and License #)

FROM BEST VALUE PHARMACY
6020A HARRIS PKWY
(817)738-0722

3-16-22
Date

MEMORANDUM FOR RECORD

FROM: [redacted] PharmD
(Name and Position)

SUBJECT: COVID-19 Vaccine Availability

1. Best Value Country Day Pharmacy (Clinic Name) currently has the following COVID-19 vaccines available for administration (check all that apply):

- ☐ Pfizer-BioNTech COMIRNATY (original formula) – BLA-licensed for ages 16+
- ☐ Pfizer-BioNTech COMIRNATY (tris-sucrose formula) – BLA-licensed for ages 16+
- ☐ Pfizer-BioNTech COVID-19 Vaccine Purple Cap (original formula) – EUA authorized for ages 12+
- ☐ Pfizer-BioNTech COVID-19 Vaccine Gray Cap (tris-sucrose formula) – EUA authorized for ages 12+
- ☐ Moderna SPIKEVAX – BLA-licensed for ages 18+
- ☒ Moderna COVID-19 Vaccine Red Cap – EUA authorized for ages 18+
- ☐ Janssen COVID-19 Vaccine Blue Cap – EUA authorized for ages 18+

2. If you have any questions, please contact me at 817-738-0722 (phone number) or _____ (email).

[redacted] PharmD [redacted]
(Name, Position and License #)

DEPARTMENT OF THE AIR FORCE
AIR FORCE RESERVE COMMAND

19 March 2022

MEMORANDUM FOR [redacted] OSS/CC

FROM: MAJ ERIC COULTER

SUBJECT: Additional Attachments to Accompany 17 March Medical Exemption Request

References: (a) Maj Eric Coulter, *Medical Exemption Request from COVID-19 Vaccination for Lack of Supply (MS)*, 17 Mar 2022
(b) Acting Assistant Secretary of Defense for Health Affairs, *Mandatory Vaccination of Service Members using the Pfizer-BioNTech COVID-19 and COMIRNATY COVID-19 Vaccines Memorandum*, 14 Sep 2021

1. I, Major Eric A. Coulter, [redacted] OSS/[redacted], DOD ID [redacted], submitted a request for Medical Exemption from the COVID-19 Vaccination for Lack of Supply (MS) to you on 17 March 2022 (reference (a)). As part of that request, an attachment was omitted which addresses one of the key points examining the Acting Assistant Secretary of Defense for Health Affairs (ASD(HA)) claim and supporting references on the "interchangeability" of the EUA Pfizer-BioNTech COVID-19 Vaccine with the fully FDA-approved (BLA-licensed) Pfizer-BioNTech COMIRNATY (COVID-19 Vaccine, mRNA) in a 14 Sep 2021 memorandum (reference (b)).

2. In paragraph 7 of my Medical Exemption Request memorandum (reference (a)), I state "The ASD(HA) memorandum dated 14 Sep 2021 **(reference** directs that "consistent with FDA guidance, DoD health care providers will use both the Pfizer-BioNTech COVID-19 vaccine and the COMIRNATY COVID-19 vaccine interchangeably for the purpose of vaccinating Service members" in accordance with the SecDef Memo (reference (a)), while also referencing an FDA Q&A website which was accessed on 10 Sep 2021. The website referenced by the ASD(HA) has changed since then, but fortunately archived versions are available **(reference (f)).**"

3. That paragraph in my memorandum should instead read "The ASD(HA) memorandum dated 14 Sep 2021 **(reference(f))** directs that "consistent with FDA guidance, DoD health care providers will use both the Pfizer-BioNTech COVID-19 Vaccine and the COMIRNATY vaccine interchangeably for the purpose of vaccinating Service members" in accordance with the SecDef Memo (reference (a)), while also referencing an FDA Q&A website which was accessed on 10 Sep 2021. The website referenced by the ASD(HA) has changed since then, but fortunately archived versions are available **(attachment 2 and 3)**."

4. This correction to paragraph 7 of my original Medical Exemption Request corrects the first error by correctly pointing to the ASD(HA) memorandum, but the change to the attachment numbering would propagate down to all the additional attachment references throughout the Medical Exemption Request requiring a rewrite. To correct this error, please consider this memorandum and its attachments as the correction verbiage and to the attachments which should have been included with the original memo.

5. The referenced attachment is a download of the archived website which the ASD(HA) quotes from and references in a footnote in the 14 Sep 2021 memorandum (reference (b)). The website (https://www.fda.gov/vaccines-blood-biologics/qa-comirnaty-covid-19-vaccine-mrna) has been changed several times since the time of the memorandum, but fortunately these pages are archived at several points close to the time of the memorandum. These archived pages can be viewed by searching for the above URL at the Internet Archive Wayback Machine (https://web.archive.org/web/) and reviewing the cached versions from 6 Sep 2021 at 19:39:59 (attachment 1) and 13 Sep 2021 at 04:27:36 (attachment 2).

6. There are no noticeable changes to the verbiage on the webpage between the two dates which bracket the date of 10 Sep 2021, which the ASD(HA) memo references as the date which the Q&A was accessed. Both archived pages \state that the content is "current as of: 09/03/2021". Each version contains the critical statements referenced in my Request for Medical Exemption: "Therefore, providers **can** use doses distributed under EUA to administer the vaccination series as if the doses were the licensed vaccine." and "Comirnaty has the same formulation as the FDA-authorized Pfizer-BioNTech COVID-19 vaccine and can be used interchangeably to provide the COVID-19 vaccination series without presenting any safety or effectiveness concerns. **The products are legally distinct with certain differences that do not impact safety or effectiveness.**"

7. If you prefer that I create a fully updated and signed version of the Medical Exemption Request memorandum which includes these corrections and attachments, or you have any questions, please contact Maj Eric Coulter at [redacted] or [redacted] @us.af.mil

COULTER.ERIC.A.[redacted] Digitally signed by COULTER.ERIC.A.[redacted] Date: 2022.03.19 19:01:14 -05'00'

ERIC A. COULTER, Maj, USAF
[redacted] Officer

2 Attachments:
1. PDF printout of archived version of FDA COMIRNATY Q&A website, 6 Sep 2021
2. PDF printout of archived version of FDA COMIRNATY Q&A website, 13 Sep 2021

Q&A for Comirnaty (COVID-19 Vaccine mRNA)

Español (https://web.archive.org/web/20210906193959/https://www.fda.gov/vaccines-blood-biologics/preguntas-y-respuestas-sobre-comirnaty-vacur

How did the FDA arrive at the decision to approve Comirnaty (COVID-19 Vaccine mRNA)? What is different now when compared to the December 2020 authorization of Pfizer-BioNTech COVID-19 Vaccine?

FDA conducted a thorough evaluation of the data and information submitted in the Biologics License Application (BLA) for Comirnaty before making a determination that the vaccine is safe and effective in preventing COVID-19 in individuals 16 years of age and older.

The EUA (https://web.archive.org/web/20210906193959/https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19) for the Pfizer-BioNTech COVID-19 Vaccine for individuals 16 years of age and older was based on safety and effectiveness data from a randomized, controlled, blinded ongoing clinical trial in approximately 18,000 individuals who received the vaccine and approximately 18,000 who received a placebo. The vaccine was 95% effective in preventing COVID-19 disease among these clinical trial participants with eight COVID-19 cases in the vaccine group and 162 in the placebo group. The duration of safety follow-up for the vaccinated and placebo participants was a median of two months after receiving the second dose.

Follow-up data from this ongoing clinical trial was analyzed by FDA to determine the safety and effectiveness of Comirnaty. The updated analysis to determine effectiveness for individuals 16 years of age and older included approximately 20,000 Comirnaty and 20,000 placebo recipients who did not have evidence of SARS-CoV-2 infection through seven days after the second dose. Overall, the vaccine was 91% effective, with 77 cases of COVID-19 occurring in the vaccine group and 833 COVID-19 cases in the placebo group.

The safety was evaluated in approximately 22,000 Comirnaty and 22,000 placebo recipients 16 years of age and older. More than half of the vaccine and placebo recipients were followed for safety for at least four months after the second dose. After issuance of the EUA, participants were unblinded in a phased manner over a period of months to offer placebo participants Comirnaty. Overall, in blinded and unblinded follow-up, approximately 12,000 Comirnaty recipients have been followed for at least 6 months.

What are the most commonly reported side effects by those who received Comirnaty (COVID-19 Vaccine mRNA)?

The most commonly reported side effects by those clinical trial participants who received Comirnaty were pain, redness and swelling at the injection site, fatigue, headache, muscle pain, chills, joint pain, and fever.

How safe and effective is Comirnaty (COVID-19 Vaccine mRNA)?

Overall, the vaccine was 91% effective in preventing COVID-19 disease, with 77 cases of COVID-19 occurring in the vaccine group and 833 COVID-19 cases in the placebo group.

The most commonly reported side effects by those clinical trial participants who received Comirnaty were pain, redness and swelling at the injection site, fatigue, headache, muscle pain, chills, joint pain and fever.

The FDA conducted a rigorous evaluation of the of post-authorization safety surveillance data pertaining to myocarditis and pericarditis following administration of Pfizer-BioNTech COVID-19 Vaccine and determined that the data demonstrate increased risks, particularly within the seven days following the second dose. The observed risk is higher among males under 40 years of age compared to females and older males. The observed risk is highest in males 12 through 17 years of age. Available data from short-term follow-up suggest that most individuals have had resolution of symptoms. However, some individuals required intensive care support Information is not yet available about potential long-term health outcomes. The Comirnaty Prescribing Information (/web/20210906193959/https://www.fda.gov/media/151707/download) includes a warning about these risks.

Will the emergency use authorization (EUA) for Pfizer-BioNTech COVID-19 Vaccine remain in effect after the approval?

The EUA will continue to cover adolescents 12 through 15 years of age (https://web.archive.org/web/20210906193959/https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use) and the administration of a third dose to certain immunocompromised individuals 12 years of age and older. Additionally, for logistical reasons, the EUA will continue to cover the use of the Pfizer-BioNTech COVID 19 Vaccine in individuals 16 years of age and older; this use is also now approved.

How is Comirnaty (COVID-19 VACCINE, mRNA) related to the PFIZER-BIONTECH COVID-19 VACCINE?

The FDA-approved Pfizer-BioNTech product Comirnaty (/web/20210906193959/https://www.fda.gov/vaccines-blood-biologics/comirnaty) (COVID-19 Vaccine, mRNA) and the FDA-authorized Pfizer-BioNTech COVID-19 Vaccine under EUA have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series without presenting any safety or effectiveness concerns. Therefore, providers can use doses distributed under EUA to administer the vaccination series as if the doses were the licensed vaccine. For purposes of administration, doses distributed under the EUA are interchangeable with the licensed doses. The Vaccine Information Fact Sheet for Recipients and Caregivers

(/web/20210906193959/https://www.fda.gov/media/144414/download) provides additional information about both the approved and authorized vaccine.

After FDA granted the emergency use authorization of the Pfizer BioNTech COVID-19 Vaccine were clinical trial participants unblinded so that the placebo recipients could be offered the vaccine?

Yes. After issuance of the EUA, clinical trial participants were unblinded in a phased manner over a period of months to offer the authorized Pfizer-BioNTech COVID-19 Vaccine to placebo participants. These participants were followed for safety outcomes. Overall, in blinded and unblinded follow-up, approximately 12,000 Pfizer-BioNTech COVID-19 Vaccine recipients have been followed for at least 6 months.

How long will Comirnaty provide protection?

Data are not yet available to inform about the duration of protection that the vaccine will provide.

Can people who have already had COVID-19 get Comirnaty?

Yes. Available data suggest that previously infected individuals can be at risk of COVID-19 (i.e., reinfection) and could benefit from vaccination.

If a person has received Comirnaty, will the vaccine protect against transmission of SARS-CoV-2 from individuals who are infected despite vaccination?

Most vaccines that protect from viral illnesses also reduce transmission of the virus that causes the disease by those who are vaccinated. While it is hoped this will be the case, the scientific community does not yet know if Comirnaty will reduce such transmission.

Is Comirnaty Vaccine interchangeable with other COVID-19 vaccines?

Comirnaty has the same formulation as the FDA-authorized Pfizer-BioNTech COVID-19 vaccine and can be used interchangeably to provide the COVID-19 vaccination series without presenting any safety or effectiveness concerns. The products are legally distinct with certain differences that do not impact safety or effectiveness.

There are no data available on the interchangeability of Comirnaty with either Moderna COVID-19 Vaccine or Janssen COVID-19 Vaccine.

Individuals who have received one dose of Moderna COVID-19 Vaccine should receive a second dose of Moderna COVID-19 Vaccine to complete the vaccination series.

Can Comirnaty cause infertility in women?

There is no scientific evidence to suggest that the vaccine could cause infertility in women. In addition, infertility is not known to occur as a result of natural COVID-19 disease, further demonstrating that immune responses to the virus, whether induced by infection or a vaccine, are not a cause of infertility. Reports on social media have falsely asserted that the vaccine could cause infertility in women and the FDA is concerned that this misinformation may cause women to avoid vaccination to prevent COVID-19, which is a potentially serious and life-threatening disease. SARS-CoV-2 is the virus that causes COVID-19. The symptoms of COVID-19 vary and are unpredictable; many people have no symptoms or only mild disease, while some have severe respiratory disease including pneumonia and acute respiratory distress syndrome (ARDS), leading to multi-organ failure and death. Comirnaty is a mRNA vaccine. It contains a piece of the SARS-CoV-2 virus's genetic material that instructs cells in the body to make the virus's distinctive "spike" protein. After a person is vaccinated, their body produces copies of the spike protein, which does not cause disease, and triggers the immune system to learn to react defensively, producing an immune response against SARS-CoV-2. Contrary to false reports on social media, this protein is not the same as any involved in the formation of the placenta.

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1. Vaccines, Blood & Biologics

Q&A for Comirnaty (COVID-19 Vaccine mRNA)

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Español

How did the FDA arrive at the decision to approve Comirnaty (COVID-19 Vaccine mRNA)? What is different now when compared to the December 2020 authorization of Pfizer-BioNTech COVID-19 Vaccine?

FDA conducted a thorough evaluation of the data and information submitted in the Biologics License Application (BLA) for Comirnaty before making a determination that the vaccine is safe and effective in preventing COVID-19 in individuals 16 years of age and older.

The EUA for the Pfizer-BioNTech COVID-19 Vaccine for individuals 16 years of age and older was based on safety and effectiveness data from a randomized, controlled, blinded ongoing clinical trial in approximately 18,000 individuals who received the vaccine and approximately 18,000 who received a placebo. The vaccine was 95% effective in preventing COVID-19 disease among these clinical trial participants with eight COVID-19 cases in the vaccine group and 162 in the placebo group. The duration of safety follow-up for the vaccinated and placebo participants was a median of two months after receiving the second dose.

Follow-up data from this ongoing clinical trial was analyzed by FDA to determine the safety and effectiveness of Comirnaty. The updated analysis to determine effectiveness for individuals 16 years of age and older included approximately 20,000 Comirnaty and 20,000 placebo recipients who did not have evidence of SARS-CoV-2 infection through seven days after the second dose. Overall, the vaccine was 91% effective, with 77 cases of COVID-19 occurring in the vaccine group and 833 COVID-19 cases in the placebo group.

The safety was evaluated in approximately 22,000 Comirnaty and 22,000 placebo recipients 16 years of age and older. More than half of the vaccine and placebo recipients were followed for safety for at least four months after the second dose. After issuance of the EUA, participants were unblinded in a phased manner over a period of months to offer placebo participants Comirnaty. Overall, in blinded and unblinded follow-up, approximately 12,000 Comirnaty recipients have been followed for at least 6 months.

What are the most commonly reported side effects by those who received Comirnaty (COVID-19 Vaccine mRNA)?

The most commonly reported side effects by those clinical trial participants who received Comirnaty were pain, redness and swelling at the injection site, fatigue, headache, muscle pain, chills, joint pain, and fever.

How safe and effective is Comirnaty (COVID-19 Vaccine mRNA)?

Overall, the vaccine was 91% effective in preventing COVID-19 disease, with 77 cases of COVID-19 occurring in the vaccine group and 833 COVID-19 cases in the placebo group.

The most commonly reported side effects by those clinical trial participants who received Comirnaty were pain, redness and swelling at the injection site, fatigue, headache, muscle pain, chills, joint pain and fever.

The FDA conducted a rigorous evaluation of the of post-authorization safety surveillance data pertaining to myocarditis and pericarditis following administration of Pfizer-BioNTech COVID-19 Vaccine and determined that the data demonstrate increased risks, particularly within the seven days following the second dose. The observed risk is higher among males under 40 years of age compared to females and older males. The observed risk is highest in males 12 through 17 years of age. Available data from short-term follow-up suggest that most individuals have had resolution of symptoms. However, some individuals required intensive care support Information is not yet available about potential long-term health outcomes. The Comirnaty Prescribing Information includes a warning about these risks.

Will the emergency use authorization (EUA) for Pfizer-BioNTech COVID-19 Vaccine remain in effect after the approval?

The EUA will continue to cover adolescents 12 through 15 years of age and the administration of a third dose to certain immunocompromised individuals 12 years of age and older. Additionally, for logistical reasons, the EUA will continue to cover the use of the Pfizer-BioNTech COVID 19 Vaccine in individuals 16 years of age and older; this use is also now approved.

How is Comirnaty (COVID-19 VACCINE, mRNA) related to the PFIZER-BIONTECH COVID-19 VACCINE?

The FDA-approved Pfizer-BioNTech product Comirnaty (COVID-19 Vaccine, mRNA) and the FDA-authorized Pfizer-BioNTech COVID-19 Vaccine under EUA have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series without presenting any safety or effectiveness concerns. Therefore, providers can use doses distributed under EUA to administer the vaccination series as if the doses were the licensed vaccine. For purposes of administration, doses distributed under the EUA are interchangeable with the licensed doses. The Vaccine Information Fact Sheet for Recipients and Caregivers provides additional information about both the approved and authorized vaccine.

After FDA granted the emergency use authorization of the Pfizer BioNTech COVID-19 Vaccine were clinical trial participants unblinded so that the placebo recipients could be offered the vaccine?

Yes. After issuance of the EUA, clinical trial participants were unblinded in a phased manner over a period of months to offer the authorized Pfizer-BioNTech COVID-19 Vaccine to placebo participants. These participants were followed for safety outcomes. Overall, in blinded and unblinded follow-up, approximately 12,000 Pfizer-BioNTech COVID-19 Vaccine recipients have been followed for at least 6 months.

How long will Comirnaty provide protection?

Data are not yet available to inform about the duration of protection that the vaccine will provide.

Can people who have already had COVID-19 get Comirnaty?

Yes. Available data suggest that previously infected individuals can be at risk of COVID-19 (i.e., reinfection) and could benefit from vaccination.

If a person has received Comirnaty, will the vaccine protect against transmission of SARS-CoV-2 from individuals who are infected despite vaccination?

Most vaccines that protect from viral illnesses also reduce transmission of the virus that causes the disease by those who are vaccinated. While it is hoped this will be the case, the scientific community does not yet know if Comirnaty will reduce such transmission.

Is Comirnaty Vaccine interchangeable with other COVID-19 vaccines?

Comirnaty has the same formulation as the FDA-authorized Pfizer-BioNTech COVID-19 vaccine and can be used interchangeably to provide the COVID-19 vaccination series without presenting any safety or effectiveness concerns. The products are legally distinct with certain differences that do not impact safety or effectiveness.

There are no data available on the interchangeability of Comirnaty with either Moderna COVID-19 Vaccine or Janssen COVID-19 Vaccine.

Individuals who have received one dose of Moderna COVID-19 Vaccine should receive a second dose of Moderna COVID-19 Vaccine to complete the vaccination series.

Can Comirnaty cause infertility in women?

There is no scientific evidence to suggest that the vaccine could cause infertility in women. In addition, infertility is not known to occur as a result of natural COVID-19 disease, further demonstrating that immune responses to the virus, whether induced by infection or a vaccine, are not a cause of infertility. Reports on social media have falsely asserted that the vaccine could cause infertility in women and the FDA is concerned that this misinformation may cause women to avoid vaccination to prevent COVID-19, which is a potentially serious and life-threatening disease. SARS-CoV-2 is the virus that causes COVID-19. The symptoms of COVID-19 vary and are unpredictable; many people have no symptoms or only mild disease, while some have severe respiratory disease including pneumonia and acute respiratory distress syndrome (ARDS), leading to multi-organ failure and death. Comirnaty is a mRNA vaccine. It contains a piece of the SARS-CoV-2 virus's genetic material that instructs cells in the body to make the virus's distinctive "spike" protein. After a person is vaccinated, their body produces copies of the spike protein, which does not cause disease, and triggers the immune system to learn to react defensively, producing an immune response against SARS-CoV-2. Contrary to false reports on social media, this protein is not the same as any involved in the formation of the placenta.

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