Covid 19 Vaccine Mandate: Key Points Presentation

The DoD does not have the properly licensed and labeled vaccine guaranteed by Secretary Austin's memo

All vaccines currently mandated remain under Emergency Use, and are a direct violation of 10 USC 1107a

Terry Adirim has acted outside her scope of authority, and issued an unenforceable directive that did not adequately explain legal protocol for administering EUA doses to Service Members

FDA guidance referenced by Terry Adirim on interchangeability does not remove the right "to accept or refuse" an EUA product

The Public Health and Service Act clearly defines the regulations of biologics and interchangeable products

FDA has failed to meet this legal standard of "Interchangeable" and licensure for 10 USC 1107a purposes

Title 21 determines a product is misbranded if its NDC code is used to denote or imply approval
e.g. "BLA Compliant" or "BLA Approved" lots found in the Dear HCP letter

Prior to FDA approval, the vaccine was not maintaining required efficacy and there were significant rises in breakthrough cases.
Making the Covid 19 Vaccine mandate for Service Members capricious and arbitrary

There is no policy to deny service members exemptions or any provisions listed in AR 40-562

CDC MMWR

There is no statistically significant difference between previous infection and previous infection with vaccination

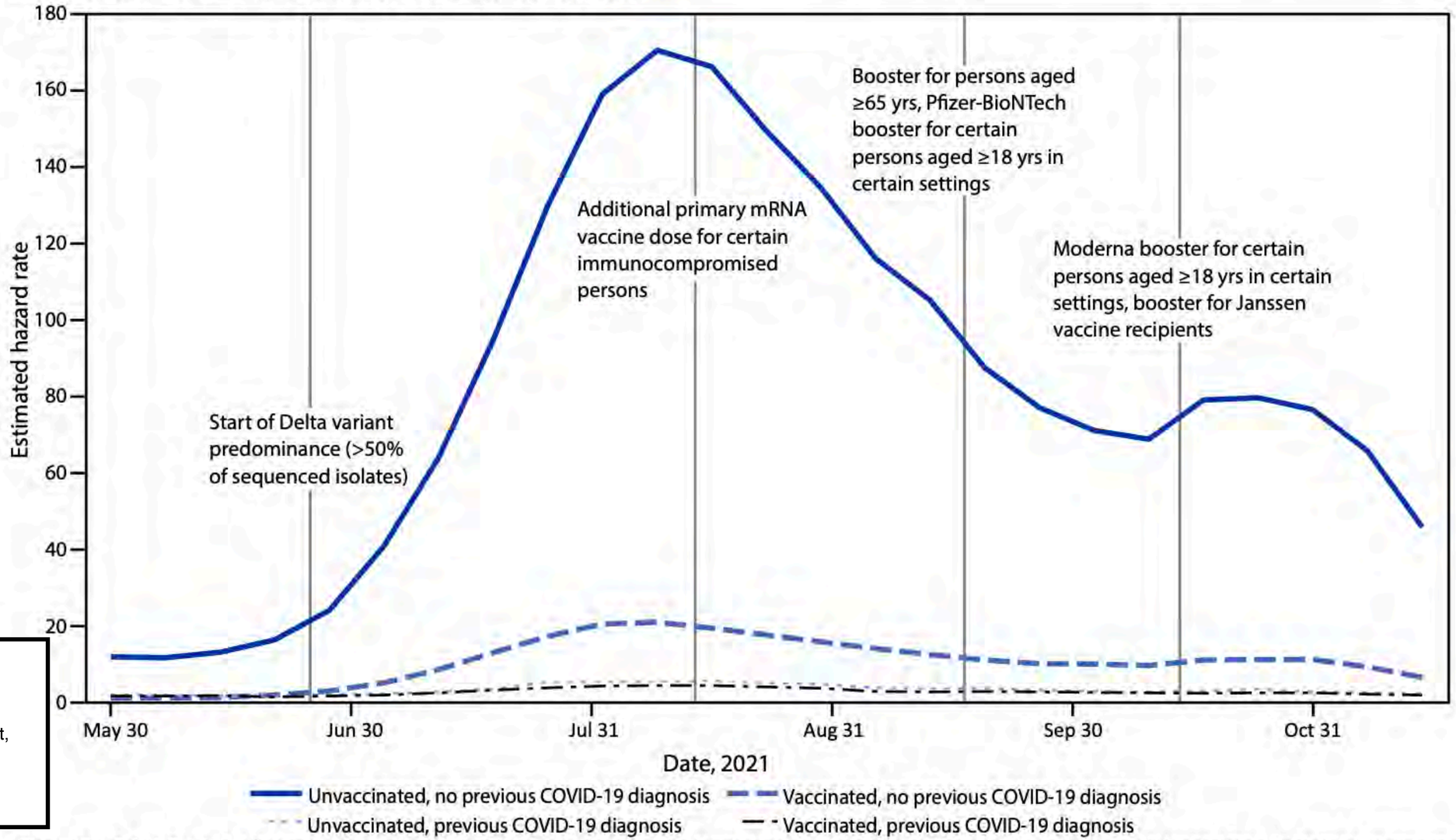
This demonstrates that it is the previous infection that incurs the most protection

Vaccination provides no added protection once recovered

The CDC stated,

"Importantly, infection-derived protection was greater after the highly transmissible Delta variant became predominant, coinciding with early declining of vaccine-induced immunity in many persons"

SUPPLEMENTARY FIGURE 1. Rates of incident laboratory-confirmed COVID-19 cases among immunologic cohorts, by vaccination and previous diagnosis histories — California, May 30–November 20, 2021*,†,§



* The SARS-CoV-2 B.1.617.2 (Delta) variant exceeded 50% of sequences in U.S. Department of Health and Human Services Region 9 (containing California) during the week of June 26. https://covid.cdc.gov/covid-data-tracker/#variant-proportions

† Estimated hazard rate is laboratory-confirmed COVID-19 cases per 100,000 person-days.

§ https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

https://stacks.cdc.gov/view/cdc/113253

https://www.cdc.gov/mmwr/volumes/71/wr/mm7104e1.htm?s_cid=mm7104e1_w

Current DoD Data

August 24, 2021 Department of Defense Coronavirus Data:
Active Duty
Cases: 226,510
Hospitlizations: 2,036
Deaths: 34

https://www.defense.gov/Spotlights/Coronavirus-DoD-Response/

DOD COVID-19 CUMULATIVE TOTALS

	Cases	Hospitalized	Recovered	Deaths
Military	392,353	2,592	378,988	94
Civilian	121,091	2,358	106,231	414
Dependent	61,357	552	55,110	35
Contractor	35,532	759	32,406	139
Total	610,333	6,261	572,735	682

The findings in this report are subject to at least four limitations. First, data from this report are insufficient to draw conclusions about the effectiveness of COVID-19 vaccines against SARS-CoV-2, including the Delta variant, during this outbreak. As population-level vaccination coverage increases, vaccinated persons are likely to represent a larger proportion of COVID-19 cases. Second, asymptomatic breakthrough infections might be underrepresented because of detection bias. Third, demographics of cases likely reflect those of attendees at the public gatherings, as events were marketed to adult male participants; further study is underway to identify other population characteristics among cases, such as additional demographic characteristics and underlying health conditions including immunocompromising conditions.*** MA DPH, CDC, and affected jurisdictions are collaborating in this response; MA DPH is conducting additional case investigations, obtaining samples for genomic sequencing, and linking case information with laboratory data and vaccination history. Finally, Ct values obtained with SARS-CoV-2 qualitative RT-PCR diagnostic tests might provide a crude correlation to the amount of virus present in a sample and can also be affected by factors other than viral load.††† Although the assay used in this investigation was not validated to provide quantitative results, there was no significant difference between the Ct values of samples collected from breakthrough cases and the other cases. This might mean that the viral load of vaccinated and unvaccinated persons infected with SARS-CoV-2 is also similar. However, microbiological studies are required to confirm these findings. https://www.cdc.gov/mmwr/volumes/70/wr/mm7031e2.htm

July 30, 2021
CDC MMWR Update
Noting viral load is similar
in vaccinated vs.
unvaccinated
As vaccination increased
so did cases of Covid 19 in the
vaccinated population

This outbreak led to the
Updated mask guidance by CDC

FDA Pfizer-BioNTech
Authorization letter

Instead of re-evaluating efficacy
to meet the FDA'S required 50%
efficacy requirement
FDA moved to boosters
within 1 month post approval

Efficacy Failures

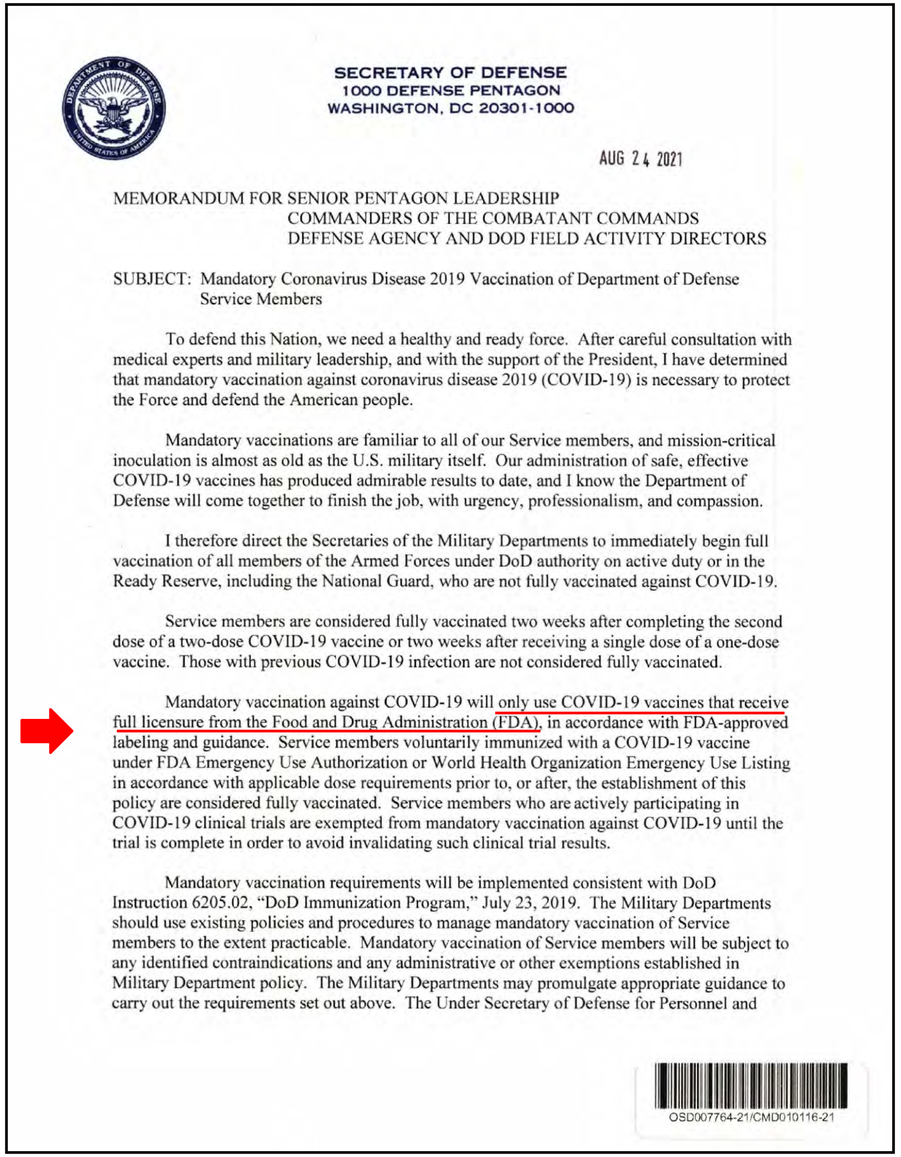
For the December 9, 2021 authorization expanding the eligible population for the homologous booster doses to individuals 16 years of age and older, FDA reviewed: data submitted previously by the sponsor to support the September 22, 2021 and November 19, 2021 authorization of a homologous booster dose under EUA; real-world data, which includes data that indicates increasing COVID-19 cases in the United States amongst vaccinated and unvaccinated individuals, and data suggesting a decreased risk of myocarditis following administration of Pfizer-BioNTech COVID-19 Vaccine booster doses compared with second primary series doses among vaccinated individuals; and a benefit-risk assessment from the sponsor, to support the expansion of the population eligible for a Pfizer-BioNTech COVID-19 Vaccine homologous booster dose to include all individuals 16 years of age and older who completed the primary series at least 6 months previously. Based on the totality of the scientific evidence available, FDA concluded that a homologous booster dose of the Pfizer-BioNTech COVID-19 Vaccine may be effective, and that the known and potential benefits of the booster dose of the Pfizer-BioNTech COVID-19 Vaccine following completion of primary vaccination with Pfizer-BioNTech COVID-19 Vaccine outweigh the known and potential risks in individuals 16 years of age and older.

https://www.fda.gov/media/150386/download

THE ORDER

On August 24, 2021 Secretary of Defense Lloyd Austin signed a memo for the mandatory vaccination against Covid 19 for all Service Members

This memo explicitly states that the only vaccines for use will, ***"Receive full licensure from the Food and Drug Administration (FDA), in accordance with FDA-approved labeling and guidance."***



SECRETARY OF DEFENSE
1000 DEFENSE PENTAGON
WASHINGTON, DC 20301-1000

AUG 24 2021

MEMORANDUM FOR SENIOR PENTAGON LEADERSHIP
COMMANDERS OF THE COMBATANT COMMANDS
DEFENSE AGENCY AND DOD FIELD ACTIVITY DIRECTORS

SUBJECT: Mandatory Coronavirus Disease 2019 Vaccination of Department of Defense Service Members

To defend this Nation, we need a healthy and ready force. After careful consultation with medical experts and military leadership, and with the support of the President, I have determined that mandatory vaccination against coronavirus disease 2019 (COVID-19) is necessary to protect the Force and defend the American people.

Mandatory vaccinations are familiar to all of our Service members, and mission-critical inoculation is almost as old as the U.S. military itself. Our administration of safe, effective COVID-19 vaccines has produced admirable results to date, and I know the Department of Defense will come together to finish the job, with urgency, professionalism, and compassion.

I therefore direct the Secretaries of the Military Departments to immediately begin full vaccination of all members of the Armed Forces under DoD authority on active duty or in the Ready Reserve, including the National Guard, who are not fully vaccinated against COVID-19.

Service members are considered fully vaccinated two weeks after completing the second dose of a two-dose COVID-19 vaccine or two weeks after receiving a single dose of a one-dose vaccine. Those with previous COVID-19 infection are not considered fully vaccinated.

Mandatory vaccination against COVID-19 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 in accordance with applicable dose requirements prior to, or after, the establishment of this policy are considered fully vaccinated. Service members who are actively participating in COVID-19 clinical trials are exempted from mandatory vaccination against COVID-19 until the trial is complete in order to avoid invalidating such clinical trial results.

Mandatory vaccination requirements will be implemented consistent with DoD Instruction 6205.02, "DoD Immunization Program," July 23, 2019. The Military Departments should use existing policies and procedures to manage mandatory vaccination of Service members to the extent practicable. Mandatory vaccination of Service members will be subject to any identified contraindications and any administrative or other exemptions established in Military Department policy. The Military Departments may promulgate appropriate guidance to carry out the requirements set out above. The Under Secretary of Defense for Personnel and

OSD007764-21/CMD010116-21

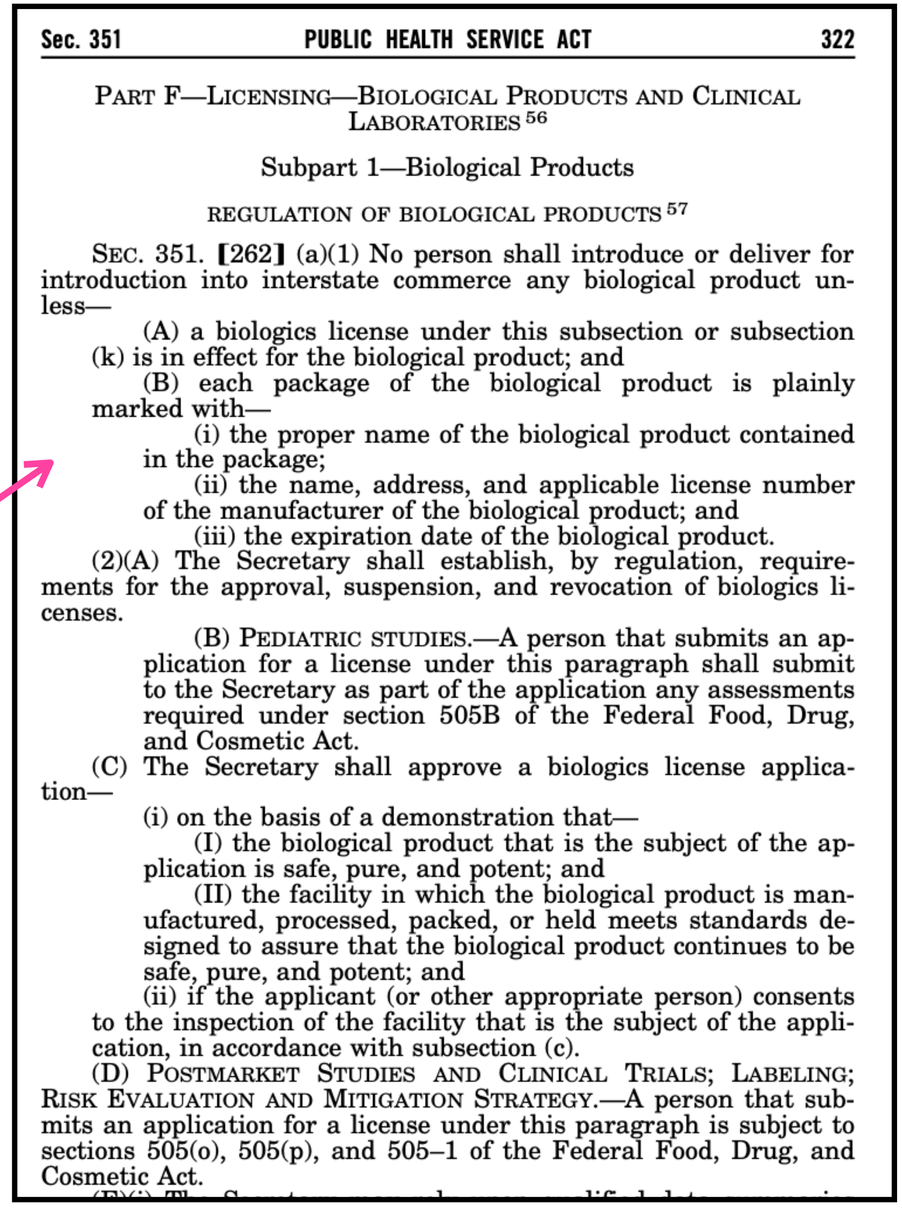
Ask yourself:

➢ *Do you know if the military is receiving fully approved product, or are other products being used as substitutes?*

1. https://media.defense.gov/2021/Aug/25/2002838826/-1/-1/0/MEMORANDUM-FOR-MANDATORY-CORONAVIRUS-DISEASE-2019-VACCINATION-OF-DEPARTMENT-OF-DEFENSE-SERVICE-MEMBERS.PDF

FULLY LICENSED

List of labeling requirements in the PHSA



Sec. 351 PUBLIC HEALTH SERVICE ACT 322

PART F—LICENSING—BIOLOGICAL PRODUCTS AND CLINICAL LABORATORIES [56]

Subpart 1—Biological Products

REGULATION OF BIOLOGICAL PRODUCTS [57]

SEC. 351. [262] (a)(1) No person shall introduce or deliver for introduction into interstate commerce any biological product unless—

(A) a biologics license under this subsection or subsection (k) is in effect for the biological product; and

(B) each package of the biological product is plainly marked with—

(i) the proper name of the biological product contained in the package;

(ii) the name, address, and applicable license number of the manufacturer of the biological product; and

(iii) the expiration date of the biological product.

(2)(A) The Secretary shall establish, by regulation, requirements for the approval, suspension, and revocation of biologics licenses.

(B) PEDIATRIC STUDIES.—A person that submits an application for a license under this paragraph shall submit to the Secretary as part of the application any assessments required under section 505B of the Federal Food, Drug, and Cosmetic Act.

(C) The Secretary shall approve a biologics license application—

(i) on the basis of a demonstration that—

(I) the biological product that is the subject of the application is safe, pure, and potent; and

(II) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent; and

(ii) if the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application, in accordance with subsection (c).

(D) POSTMARKET STUDIES AND CLINICAL TRIALS; LABELING; RISK EVALUATION AND MITIGATION STRATEGY.—A person that submits an application for a license under this paragraph is subject to sections 505(o), 505(p), and 505–1 of the Federal Food, Drug, and Cosmetic Act.

What is required to be a "fully licensed" product ?

Per the Public Health Service Act, Licensure of a Biologic is a multifaceted process:

1. Approval of a Biologics Licensing Application
2. Limited to the manufacturing process and locations that are approved in the Application submitted to the FDA
3. Labeling Requirements that are approved by the FDA

Each Label Legally **MUST** possess:

1. The Proprietary Name of the Product
2. The License Number
3. The Name and Address of the Manufacturer
4. The Expiration Date

1. https://www.law.cornell.edu/uscode/text/42/262

Exceptions To Labeling

§ 610.68 Exceptions or alternatives to labeling requirements for biological products held by the Strategic National Stockpile.

(a) The appropriate FDA Center Director may grant an exception or alternative to any provision listed in paragraph (f) of this section and not explicitly required by statute, for specified lots, batches, or other units of a biological product, if the Center Director determines that compliance with such labeling requirement could adversely affect the safety, effectiveness, or availability of such product that is or will be included in the Strategic National Stockpile.

Title 21 prohibits any exceptions to labeling when it is specifically required by the statute

All biologics licensing is subject to the labeling and manufacturing requirements as described in the Public Health Service Act

The Federal Food and Drug Administration does not have the legal authority for “enforcement discretion” when the requirement is clearly defined in the statute

https://www.ecfr.gov/current/title-21/chapter-I/subchapter-F/part-610/subpart-G/section-610.68

(a) The appropriate FDA Center Director may grant an exception or alternative to any provision listed in paragraph (f) of this section and not explicitly required by statute, for specified lots, batches, or other units of a biological product, if the Center Director determines that compliance with such labeling requirement could adversely affect the safety, effectiveness, or availability of such product that is or will be included in the Strategic National Stockpile.

(b)

(1)

(i) A Strategic National Stockpile official or any entity that manufactures (including labeling, packing, relabeling, or repackaging), distributes, or stores a biological product that is or will be included in the Strategic National Stockpile may submit, with written concurrence from a Strategic National Stockpile official, a written request for an exception or alternative described in paragraph (a) of this section to the Center Director.

(ii) The Center Director may grant an exception or alternative described in paragraph (a) of this section on his or her own initiative.

(2) A written request for an exception or alternative described in paragraph (a) of this section must:

(i) Identify the specified lots, batches, or other units of the biological product that would be subject to the exception or alternative;

(ii) Identify the labeling provision(s) listed in paragraph (f) of this section that are the subject of the exception or alternative request;

(iii) Explain why compliance with such labeling provision(s) could adversely affect the safety, effectiveness, or availability of the specified lots, batches, or other units of the biological product that are or will be included in the Strategic National Stockpile;

(iv) Describe any proposed safeguards or conditions that will be implemented so that the labeling of the product includes appropriate information necessary for the safe and effective use of the product, given the anticipated circumstances of use of the product;

(v) Provide a draft of the proposed labeling of the specified lots, batches, or other units of the biological product subject to the exception or alternative; and

(vi) Provide any other information requested by the Center Director in support of the request.

(c) The Center Director must respond in writing to all requests under this section.

(d) A grant of an exception or alternative under this section will include any safeguards or conditions deemed appropriate by the Center Director so that the labeling of product subject to the exception or alternative includes the information necessary for the safe and effective use of the product, given the anticipated circumstances of use.

(e) If you are a sponsor receiving a grant of a request for an exception or alternative to the labeling requirements under this section:

(1) You need not submit a supplement under § 601.12(f)(1) through (f)(2) of this chapter; however,

(2) You must report any grant of a request for an exception or alternative under this section as part of your annual report under § 601.12(f)(3) of this chapter.

(f) The Center Director may grant an exception or alternative under this section to the following provisions of this chapter, to the extent that the requirements in these provisions are not explicitly required by statute:

(1) § 610.60;

(2) § 610.61(c) and (e) through (r);

(3) § 610.62;

(4) § 610.63;

(5) § 610.64;

(6) § 610.65; and

(7) § 312.6.

THE PRODUCT IS NOT THERE..

SEPTEMBER 14, 2021

FRAGO 5 TO HQDA EXORD 225-21 COVID-19 STEADY STATE OPERATIONS

3.D.8.A
WHILE THE ONLY MANDATORY VACCINE IS THE PFIZER/COMIRNATY COVID-19 VACCINE

3.D.8.B.1
COMMANDERS WILL ENSURE SUFFICIENT DOSES OF DEPARTMENT OF DEFENSE APPROVED VACCINES ARE ON HAND AND AVAILABLE FOR THEIR UNIT

COVID-19 Vaccine Operations

cao 24 Jan 2022

Pfizer-BioNTech COVID-19 Vaccine Comparisons

	Purple Vial/Cap	Gray Vial/Cap	Orange Vial/Cap
Buffer	Phosphate Buffer Solution (PBS)	Tromethamine (Tris)	Tromethamine (Tris)
Age Group	12 years and older	12 years and older	5 – 11 years
FDA EUA or BLA Status*	BLA (approved 23 Aug 21) (EUA for ages 12 – 15)	BLA (approved 16 Dec 21) (EUA for ages 12 – 15)	EUA (authorized 29 Oct 21)
Part of DoD Mandate	Yes	Not yet** (per ASD(HA) & DHA)	N/A
DAF Inventory (cao 18 Jan 21) - % BLA lots - % EUA lots	89,604 doses - BLA: 13,266 (14.8%) - EUA: 76,388 (85.2%)	None	30,730 doses - BLA: N/A - EUA: 100%
Lots with COMIRNATY label	None	None	N/A

*FDA EUA (Emergency Use Authorization). BLA (Biologics License Application or "Full Approval")
**Individuals who receive Pfizer-BioNTech gray vial/cap meet the FHP requirement and can be documented in ASIMS and EHR

Integrity - Service - Excellence

18

There is no FRAGO or official DoD policy listing the Pfizer-BioNTech EUA labeled product as a mandated vaccine

Manufacturer	Pre-EUA)	Name	Description	(UOS)	Package	(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 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."
				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	
				0069-2025-25	CARTON, 25 MULTI-DOSE VIALS			

Note: EUA and BLA NDC Codes do not match

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	

If the FDA, CDC and DoD are implying that the products being distributed are the approved product, there is no evidence to support this claim

https://www.cdc.gov/vaccines/programs/iis/COVID-19-related-codes.html

BLA NDC Codes

NEWS: DailyMed Announcements

PRINT SHARE

SEPTEMBER 13, 2021

Pfizer received FDA BLA license for its COVID-19 vaccine

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 COMIRNATY and listed 2 new NDCs (0069-1000-03, 0069-1000-02) 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.

Return to News Index

August 23, 2021 approval codes
0069-1000-03
0069-1000-02

December 16, 2021 Supplement approval codes
Gray Cap Tris Buffer Formulation
Pfizer medical has determined this formulation
will maintain the Pfizer-BioNtech labeling
Violating the terms of their approval
If they are produced with EUA labels and codes

NDC CODES

COMIRNATY- covid-19 vaccine, mrna injection, suspension

If this SPL contains inactivated NDCs listed by the FDA initiated compliance action, they will be specified as such.

	NDC
1	0069-2025-01
2	0069-2025-10
3	0069-2025-25

https://dailymed.nlm.nih.gov/dailymed/index.cfm

WHAT IS THIS?

Comirnaty Prescribing Information Page on the DailyMed
PBS Buffer Formulation
Original Approval August 23, 2021

Inactive Ingredients

Ingredient Name	Strength
ALC-0159 (UNII: PJH39UMU6H)	0.4 mg in 2.25 mL
ALC-0315 (UNII: AVX8DX713V)	3.23 mg in 2.25 mL
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	0.07 mg in 2.25 mL
MONOBASIC POTASSIUM PHOSPHATE (UNII: 4J9FJ0HL51)	0.07 mg in 2.25 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	2.7 mg in 2.25 mL
SODIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: 94255I6E2T)	0.49 mg in 2.25 mL
SUCROSE (UNII: C151H8M554)	46 mg in 2.25 mL
1,2-DISTEAROYL-SN-GLYCERO-3-PHOSPHOCHOLINE (UNII: 043IPI2M0K)	0.7 mg in 2.25 mL
CHOLESTEROL (UNII: 97C5T2UQ7J)	1.4 mg in 2.25 mL
WATER (UNII: 059QF0KO0R)	

Codes Corresponding to BLA Approval

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0069-1000-02	195 in 1 CARTON		
1	NDC:0069-1000-01	2.25 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product		
2	NDC:0069-1000-03	25 in 1 CARTON		
2	NDC:0069-1000-01	2.25 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125742	08/23/2021	08/23/2021

Note the Marketing ‘Start’ and ‘End’ dates

Labeler - Pfizer Laboratories Div Pfizer Inc (134489525)

Registrant - Pfizer Inc (113480771)

Establishment

Name	Address	ID/FEI	Business Operations
Pfizer Manufacturing Belgium NV		370156507	ANALYSIS(0069-1000) , MANUFACTURE(0069-1000) , PACK(0069-1000) , LABEL(0069-1000)

Ask yourself:

➢ *Why was the Marketing ‘End’ date made to be the same as the ‘Start’ date?*

➢ *Did you know a drug can not be distributed after its Marketing End date?*

1. https://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=618348

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER F - BIOLOGICS

PART 601 -- LICENSING

Subpart A - General Provisions

Sec. 601.5 Revocation of license.

(a) A biologics license shall be revoked upon application of the manufacturer giving notice of intention to discontinue the manufacture of all products manufactured under such license or to discontinue the manufacture of a particular product for which a license is held and waiving an opportunity for a hearing on the matter.

(b)(1) The Commissioner shall notify the licensed manufacturer of the intention to revoke the biologics license, setting forth the grounds for, and offering an opportunity for a hearing on the proposed revocation if the Commissioner finds any of the following:

(i) Authorized Food and Drug Administration employees after reasonable efforts have been unable to gain access to an establishment or a location for the purpose of carrying out the inspection required under § 600.21 of this chapter,

(ii) Manufacturing of products or of a product has been discontinued to an extent that a meaningful inspection or evaluation cannot be made,

(iii) The manufacturer has failed to report a change as required by § 601.12 of this chapter,

(iv) The establishment or any location thereof, or the product for which the license has been issued, fails to conform to the applicable standards established in the license and in this chapter designed to ensure the continued safety, purity, and potency of the manufactured product,

(v) The establishment or the manufacturing methods have been so changed as to require a new showing that the establishment or product meets the requirements established in this chapter in order to protect the public health, or

(vi) The licensed product is not safe and effective for all of its intended uses or is misbranded with respect to any such use.

(2) Except as provided in § 601.6 of this chapter, or in cases involving willfulness, the notification required in this paragraph shall provide a reasonable period for the licensed manufacturer to demonstrate or achieve compliance with the requirements of this chapter, before proceedings will be instituted for the revocation of the license. If compliance is not demonstrated or achieved and the licensed manufacturer does not waive the opportunity for a hearing, the Commissioner shall issue a notice of opportunity for hearing on the matter under § 12.21(b) of this chapter.

[64 FR 56451, Oct. 20, 1999]

TITLE 21

Title 21, Ch. 1, Subchapter F, Part 601.5 goes into the revocation of a biologics license if the manufacturer states its intent to discontinue manufacture of the product they applied to have licensed

Ask yourself:

- *If Pfizer submitted an Expiration Date with their application, should FDA have revoked their Biologics License Application?*
- *What are the implications of submitting the same marketing start and end date?*

1. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-F/part-601

Is the Department of Defense carrying out a mandatory vaccination program that only has products marked for "Emergency Use"?

Mandating An EUA

DoD is relying on 2 letters to carry out the mandate:

1. The "Dear Healthcare Professional" (DHCP) letter denoting "BLA Compliant" lots. This letter has been heavily relied on by the DoD in the ongoing court cases about the current mandate. (See Coker v. Austin)

2. A memo from Terry Adirim, ASD(HA), directing DoD providers to use the EUA doses as if they were licensed product. Adirim does not refer to the Dear HCP letter, not including BLA compliant lots as part of any official DoD policy

August 23, 2021
RE: Pfizer-BioNTech COVID-19 Vaccine IMPORTANT PRODUCT INFORMATION
Certain Pfizer-BioNTech COVID-19 Vaccine Lots authorized for Emergency Use comply with the Biologics License Application (BLA)

COMIRNATY
(COVID-19 Vaccine, mRNA)

Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany
Marketing Authorization Holder

Manufactured by
Pfizer Inc.
New York, NY 11017

US License No. 2229

Dear Healthcare Professional,
Pfizer, Inc. would like to provide you with updated and very important information related to the Pfizer-BioNTech COVID-19 Vaccine, authorized for emergency use by FDA under an Emergency Use Authorization (EUA). On August 23, 2021, FDA approved BioNTech's Biologics License Application (BLA) for COMIRNATY (COVID-19 Vaccine, mRNA), under U.S. License No. 2229. Many lots of Pfizer-BioNTech COVID-19 Vaccine are in circulation that were authorized for emergency use, and are labelled in accordance with the EUA. **Some of these lots comply with the recently approved BLA for COMIRNATY and are therefore considered "BLA-approved" lots for administration to individuals 16 years of age and older.** The lots that are BLA-approved for administration may be found at cvdvaccine-us.com/resources. For these lots, please see the COMIRNATY® full prescribing information for indication and usage, dosing and administration, and important safety information. This information can be found by scanning the QR code. **Please note, it is imperative that you not discard any available EUA lots. These lots continue to be authorized for use under EUA in individuals 12 years of age and older, and for use as a third dose in certain immunocompromised individuals. You can continue to use them up to the date of expiry.**

Sincerely,

Donna Boyce
Senior Vice President, Global Regulatory Affairs

BIONTECH

Pfizer

2021TA035 v1.0

ASSISTANT SECRETARY OF DEFENSE
1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (MANPOWER AND RESERVE AFFAIRS
ASSISTANT SECRETARY OF THE NAVY (MANPOWER AND RESERVE AFFAIRS
ASSISTANT SECRETARY OF THE AIR FORCE (MANPOWER AND RESERVE AFFAIRS
DIRECTOR, DEFENSE HEALTH AGENCY

SUBJECT: Mandatory Vaccination of Service Members using the Pfizer-BioNTech COVID-19 and Comirnaty COVID-19 Vaccines

On August 23, 2021, the U.S. Food and Drug Administration (FDA) approved the biologics license application for the Comirnaty vaccine, made by Pfizer-BioNTech, as a two-dose series for prevention of coronavirus disease 2019 (COVID-19) in persons aged 16 years or older. Previously, on December 11, 2020, the FDA issued an Emergency Use Authorization (EUA) for the Pfizer-BioNTech COVID-19 vaccine, which has the same formulation as the Comirnaty vaccine. Per FDA guidance, these two vaccines are "interchangeable" and DoD health care providers should "use doses distributed under the EUA to administer the vaccination series as if the doses were the licensed vaccine."[1]

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 Secretary of Defense Memorandum, "Mandatory Coronavirus Disease 2019 Vaccination of Department of Defense Service Members," August 24, 2021.

My point of contact for this guidance is Colonel Michael J. Berecz, who may be reached at (703) 681-8463 or michael.j.berecz.mil@mail.mil.

ADIRIM.TERRY.A.1523847127 Digitally signed by ADIRIM.TERRY.A.1523847127 Date: 2021.09.14 11:02:05 -04'00'

Terry Adirim, M.D., M.P.H., M.B.A.
Acting

cc:
Surgeon General of the Army
Surgeon General of the Navy
Surgeon General of the Air Force
Joint Staff Surgeon

[1] FDA, "Q&A for Comirnaty (COVID-19 Vaccine mRNA)," https://www.fda.gov/vaccines-blood-biologics/qa-comirnaty-covid-19-vaccine-mrna, accessed September 10, 2021.

1. This Dear Health Care Professional (DHCP) letter instructs those administering certain lots of the Pfizer-BioNTech to treat them as “BLA Approved”

2. The first seven lots referenced in the “additional lot details” were manufactured prior to 23 AUG 2021, the last two were manufactured after the approval but retain EUA labels.

3. These cannot be deemed approved, or compliant, if they were manufactured before the approval date, and/or are marked with the EUA labels. Incorrect labeling violates the BLA approval and the statutory labeling requirements of the PHS Act

Ask yourself:

- *Is “BLA Compliant” a regulatory term used at the FDA?*
- *Why were 2 lots manufactured after the approval but retained EUA labels and EUA NDC’s?*
- *Why does it matter if an EUA NDC is being represented as “BLA Approved”?*

DHCP LETTER & LOT #’S

August 23, 2021
RE: Pfizer-BioNTech COVID-19 Vaccine IMPORTANT PRODUCT INFORMATION
Certain Pfizer-BioNTech COVID-19 Vaccine Lots authorized for Emergency Use comply with the Biologics License Application (BLA)

COMIRNATY® (COVID-19 Vaccine, mRNA)

Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany
Marketing Authorization Holder

Manufactured by
Pfizer Inc.
New York, NY 11017

US License No. 2229

Dear Healthcare Professional,
Pfizer, Inc. would like to provide you with updated and very important information related to the Pfizer-BioNTech COVID-19 Vaccine, authorized for emergency use by FDA under an Emergency Use Authorization (EUA). On August 23, 2021, FDA approved BioNTech’s Biologics License Application (BLA) for COMIRNATY (COVID-19 Vaccine, mRNA), under U.S. License No. 2229. Many lots of Pfizer-BioNTech COVID-19 Vaccine are in circulation that were authorized for emergency use, and are labelled in accordance with the EUA. **Some of these lots comply with the recently approved BLA for COMIRNATY and are therefore considered “BLA-approved” lots for administration to individuals 16 years of age and older.** The lots that are BLA-approved for administration may be found at cvdvaccine-us.com/resources. For these lots, please see the COMIRNATY® full prescribing information for indication and usage, dosing and administration, and important safety information. This information can be found by scanning the QR code. **Please note, it is imperative that you not discard any available EUA lots. These lots continue to be authorized for use under EUA in individuals 12 years of age and older, and for use as a third dose in certain immunocompromised individuals. You can continue to use them up to the date of expiry.**

Sincerely,

Donna Boyce
Senior Vice President, Global Regulatory Affairs

BIONTECH

Additional Lot Details – Lot Numbers

FD7220	
FE3592	
FF2587	
FF2588	Mfd before approval
FF2590	
FF2593	
FF8841	
FH8027	Mfd after approval
FH8028	

Lot # have EUA NDC Codes:
(59267-1000-02)
(59267-1000-03)

Manufacturer	NDC11 Unit of Sale: This NDC goes in NYSIIS Inventory	NDC11 Unit of Use: This NDC will be on the vi	Lot Numbe	Manufacture Date	Expiration Dat	Date Last Updated
Pfizer Inc.	59267-1000-02	59267-1000-01	FE3592	6/30/2021	2/28/2022	8/27/2021
Pfizer Inc.	59267-1000-03	59267-1000-01	FD7220	6/23/2021	11/30/2021	8/6/2021
Pfizer Inc.	59267-1000-02	59267-1000-01	FF2588	7/4/2021	3/31/2022	8/27/2021
Pfizer Inc.	59267-1000-02	59267-1000-01	FD7220	6/23/2021	2/28/2022	8/27/2021
Pfizer Inc.	59267-1000-02	59267-1000-01	FF2590	7/6/2021	3/31/2022	8/27/2021
Pfizer Inc.	59267-1000-02	59267-1000-01	FF8841	7/23/2021	3/31/2022	8/27/2021
Pfizer Inc.	59267-1000-02	59267-1000-01	FF2587	7/2/2021	3/31/2022	8/27/2021
Pfizer Inc.	59267-1000-02	59267-1000-01	FF2593	7/6/2021	3/31/2022	8/27/2021

https://www.cvdvaccine-us.com/resources

DHA Vaccine Info

All of the “BLA Doses” listed here
are marketed as EUA products
due to their corresponding
NDC’s
FDA ***legally*** designates them as an EUA

Lots FH8027 and FH8028
were produced after the August approval,
but are correlated with EUA codes
and retain EUA labels

The PHS Act does not allow for a product
to be deemed compliant
if all the statutory requirements are not met
e.g. ***labeling and manufacturing***

DOD COVID-19 VACCINE Doses on Hand

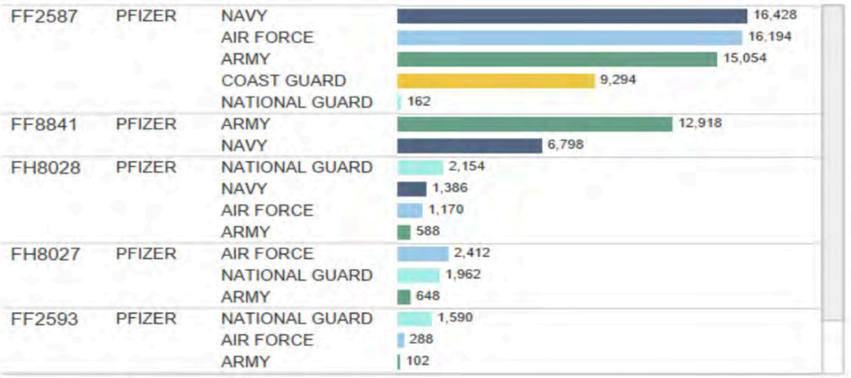
Biologic License Agreement Vaccine Quantities

Data as of: **Jan 11, 2022**

Doses or Vials	DHA Managed	CCMD	Service/Agency	DHA Market	Main Organization	BLA Lot Number	Expiration Dates
Doses	All	All	All	All	All	Multiple values	All

90,570 Current Serviceable BLA Doses by Service/Agency

Brush for details, click to filter



Current Serviceable BLA Doses by Main Organizations

Brush for details. Each circle is a main organization, listed in alphabetical order. The larger the circle, the greater the vaccine quantity.

Serviceable BLA Vials Recent Trend

BLA Lot Number	Item Name	1/11/2022	1/10/2022	1/7/2022	1/6/2022	1/5/2022	1/4/2022	1/3/2022	12/29/2021	12/28/2021	12/27/2021	12/23/2021	12/22/2021	12/21/2021
FF2587	PFIZER	57,132	57,954	59,784	60,534	60,960	61,758	62,094	64,068	64,224	64,590	64,680	65,550	67,038
FF25877	PFIZER	204	204	204	204	204	204	204	204	204	204	204	204	204
FF2590	PFIZER	1,218	1,368	1,368	1,368	1,368	1,608	1,608	1,608	1,608	1,608	1,608	1,968	1,968
FF2593	PFIZER	1,980	1,980	1,980	1,980	1,980	1,980	1,980	1,992	1,992	1,992	1,992	1,692	1,692
FF8841	PFIZER	19,716	19,824	20,532	20,736	20,976	21,072	21,096	21,300	21,444	21,444	21,528	21,702	21,840
FH8027	PFIZER	5,022	5,658	5,664	6,060	6,510	6,570	7,812	8,346	8,502	8,868	8,868	9,990	10,212
FH8028	PFIZER	5,298	5,406	5,406	5,418	5,418	5,484	5,484	5,538	5,592	5,592	5,796	6,276	6,306

As of 2022-01-11
POC: Col Jennifer Garrison
E-mail: jennifer.h.garrison.mil@mail.mil

DMLSS/SLEP
Data current as of 11 Jan 22

DHA Vaccine Info Part 2

CONTROLLED UNCLASSIFIED INFORMATION (CUI)

IHD

COVID vaccine implementation updates 12 Jan 2022

- Potential issue: Pfizer-BioNTech supply to support mandate
  - 350K "plus up" of purple-cap was approved by DHA and by CAG
  - CAG now pushing back, stating that the purple and gray cap products are interchangeable
  - Current status
    - ✓ Estimated SM need to reach 100%: **700K doses**; for ADSM: **162K doses**
    - ✓ Pfizer product on the shelf which may be used for mandate: **390K total doses**
      - EUA-manufactured, EUA-labeled: 300K doses
      - BLA-manufactured, EUA-labeled: 90K doses
    - ✓ Requested mtng with CAG/CDC/OGC/DHA 11 Jan 2022
    - ✓ Alternatives:
      - Immediate ceasing of administering purple cap for non-SM
        - » Tris be ordered and directed to non-SM
      - Strongly encourage Pfizer/CDC to publically identify BLA-approved Tris lots
      - Provide "Comirnaty"-labeled vaccine
      - Await Moderna BLA approval by FDA

Both of these distinctions violate the August 24, 2021 memo by Secretary Austin, and the ***statutory*** requirements for licensure

January 2022 continued

DHA Vaccine Info Part 3

The change presented from January to February is notable.
DHA is no longer distinguishing EUA labeled lots that are “BLA Compliant”,
and have added Pediatric doses to this total despite no BLA approval

Who at DHA has decided that all EUA products are to be added as “Biologics License Agreement Vaccine Quantities”?

This 500,000 increase demonstrates further that EUA products are being used to satisfy the mandate

To date: Comirnaty and SpikeVax have not been produced under the terms of the Biologics License Application Approval

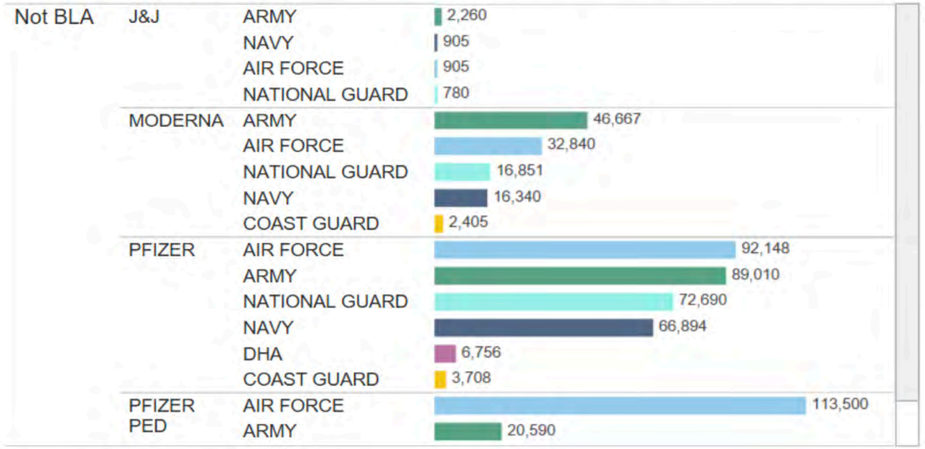
The legal implication here is a continued violation 10 USC 1107a

Approval does not equal availability

Biologic License Agreement Vaccine Quantities

Doses or Vials	DHA Managed	CCMD	Service/Agency	DHA Market	Main Organization	BLA Lot Number	Expiration Dates
Doses	All	All	All	All	All	Not BLA	All

594,089 Current Serviceable BLA Doses by **Service/Agency**
Brush for details, click to filter



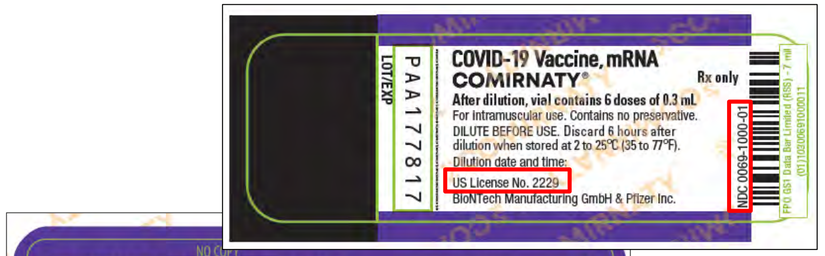
Current Serviceable BLA Doses by **Main Organizations** Brush for details. Each circle is a main organization, listed in alphabetical order. The larger the circle, the greater the vaccine quantity.

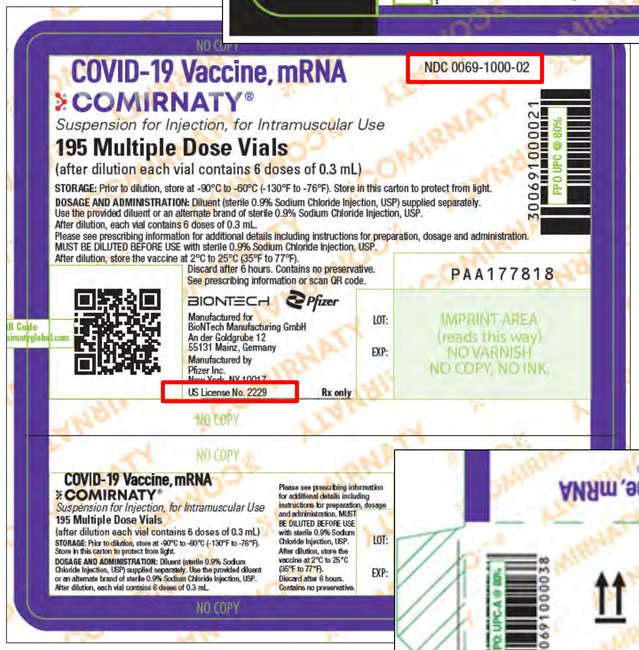
Serviceable BLA Vials Recent Trend

BLA Lot Number	Item Name	2/8/2022	2/7/2022	2/4/2022	2/3/2022	2/2/2022	2/1/2022	1/31/2022	1/28/2022	1/27/2022	1/26/2022	1/25/2022	1/24/2022	1/21/2022	1/20/2022	1/19/2022	1/18/2022
Not BLA	J&J	4,855	4,850	4,850	4,850	4,870	4,950	4,955	4,970	4,975	4,975	4,975	5,040	4,675	4,900	5,050	5,050
	MODERNA	115,623	115,103	116,793	117,673	129,095	131,156	136,277	114,817	103,005	90,715	90,601	89,001	90,841	89,593	90,781	90,781
	PFIZER	327,360	331,206	332,580	332,388	331,452	331,452	328,380	328,968	299,880	306,948	310,518	309,564	305,208	302,484	300,762	300,654
	PFIZER PED	144,760	142,930	143,210	149,320	150,280	150,280	154,660	157,780	147,540	147,380	147,730	147,880	148,160	147,230	153,780	153,780

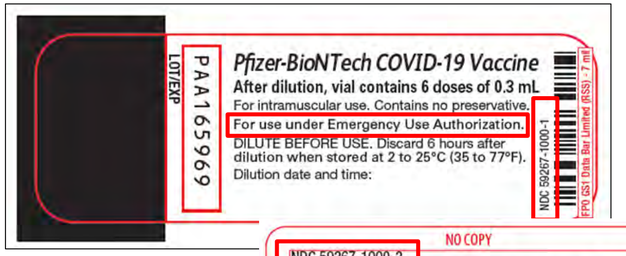
EUA v APPROVED PACKAGING

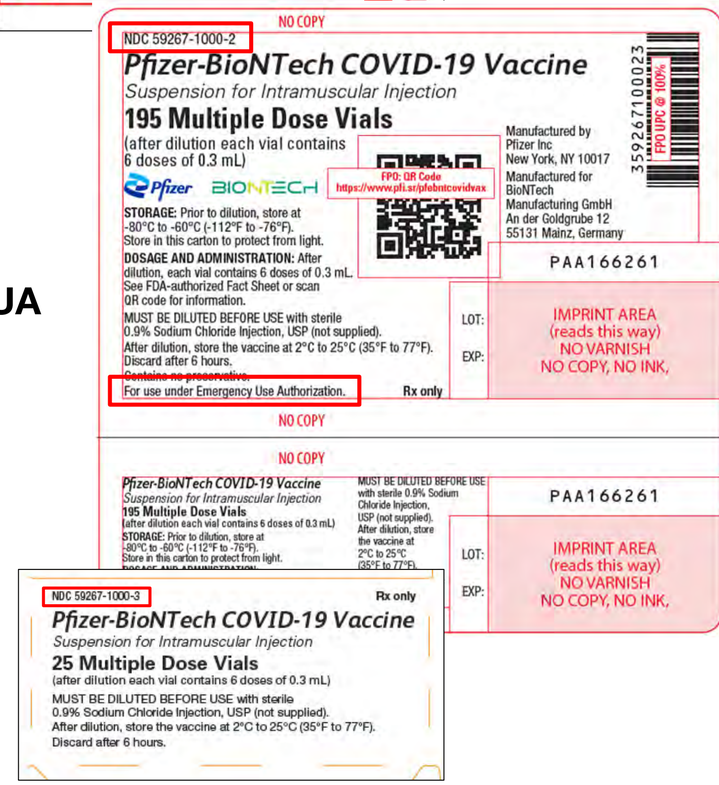
COMIRNATY (FDA Approved)





APPROVED VS. EUA





Pfizer-BioNTech COVID-19 Vaccine (EUA)

Labeling requirement BLA approval letter excerpt

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the final content of labeling (21 CFR 601.14) in Structured Product Labeling (SPL) format via the FDA automated drug registration and listing system, (eLIST) as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the Package Insert submitted on August 21, 2021. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As* at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

BLUF: If labeling is not identical it is not a BLA compliant product, As it blatantly violates the terms of the approval

https://www.fda.gov/media/151710/download

1. https://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=595377

21 USC SEC 207.37c

The Implication of Using EUA NDC's as "BLA Approved"

Title 21, Chapter 1, Subchapter C, §207.37c - What restrictions pertain to the use of the NDC?

(a) A product may be deemed to be *misbranded* if an NDC is used:

(1) To represent a different drug than the drug for which the NDC has been assigned, as described in § 207.33;

(2) **To denote or imply FDA approval of a drug; or**

(3) On products that are not subject to parts 207, 607 of this chapter, or 1271 of this chapter, such as dietary supplements and medical devices.

(b) If marketing is resumed for a discontinued drug, and no changes have been made to the drug that would require a new NDC under § 207.35, the drug must have the same NDC that was assigned to it as described in § 207.33, before marketing was discontinued.

1. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-207/subpart-C/section-207.37

THE MEMO BY TERRY ADIRIM

1.This memo is in conflict with the guarantees presented within Secretary Austin's memo

2. Terry Adirim does *not* have the legal authority to instruct any personnel to administer an EUA as if it is licensed. This authority is left solely to the discretion of the President.

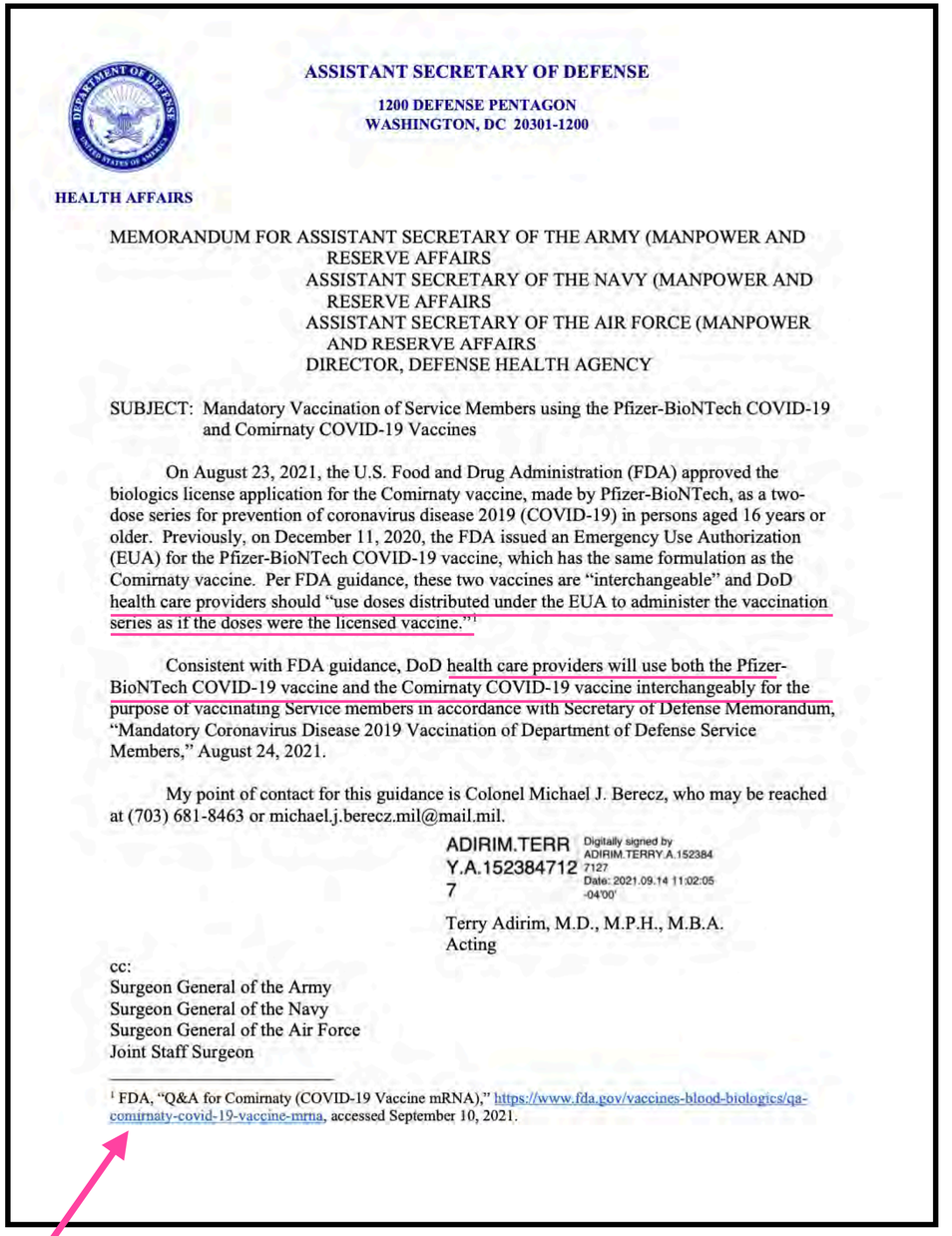
3. The President has not signed any waivers to "accept or refuse" administration of an EUA

4. There is a claim made in this memo that these products ***SHOULD*** and ***WILL*** be used "***interchangeably***."

5. "Should" and "will" denote a requirement. Adirim by saying "will" she is mandating an EUA https://www.esd.whs.mil/Portals/54/Documents/DD/iss_process/standards/DoD%20Issuance%20Style%20Guide.pdf?ver=byL0j89zKtgiXVja2VlV0Q%3D%3D

6. The Comirnaty/Spikevax page in the FDA PurpleBook does not list the Pfizer-Biontech or Moderna Covid 19 vaccine as a biosimilar or an "interchangeable."

7. Adirim's memo makes no mention of exclusively using "BLA Complaint" lots. The DoD has contended in court it is only mandating these lots, but there is no mention of that in any documentation for administration of EUA labeled vaccines



ASSISTANT SECRETARY OF DEFENSE
1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (MANPOWER AND RESERVE AFFAIRS)
ASSISTANT SECRETARY OF THE NAVY (MANPOWER AND RESERVE AFFAIRS)
ASSISTANT SECRETARY OF THE AIR FORCE (MANPOWER AND RESERVE AFFAIRS)
DIRECTOR, DEFENSE HEALTH AGENCY

SUBJECT: Mandatory Vaccination of Service Members using the Pfizer-BioNTech COVID-19 and Comirnaty COVID-19 Vaccines

On August 23, 2021, the U.S. Food and Drug Administration (FDA) approved the biologics license application for the Comirnaty vaccine, made by Pfizer-BioNTech, as a two-dose series for prevention of coronavirus disease 2019 (COVID-19) in persons aged 16 years or older. Previously, on December 11, 2020, the FDA issued an Emergency Use Authorization (EUA) for the Pfizer-BioNTech COVID-19 vaccine, which has the same formulation as the Comirnaty vaccine. Per FDA guidance, these two vaccines are "interchangeable" and DoD health care providers should "use doses distributed under the EUA to administer the vaccination series as if the doses were the licensed vaccine."[1]

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 Secretary of Defense Memorandum, "Mandatory Coronavirus Disease 2019 Vaccination of Department of Defense Service Members," August 24, 2021.

My point of contact for this guidance is Colonel Michael J. Berecz, who may be reached at (703) 681-8463 or michael.j.berecz.mil@mail.mil.

ADIRIM.TERRY.A.1523847127 Digitally signed by ADIRIM.TERRY.A.1523847127 Date: 2021.09.14 11:02:05 -04'00'

Terry Adirim, M.D., M.P.H., M.B.A.
Acting

cc:
Surgeon General of the Army
Surgeon General of the Navy
Surgeon General of the Air Force
Joint Staff Surgeon

[1] FDA, "Q&A for Comirnaty (COVID-19 Vaccine mRNA)," https://www.fda.gov/vaccines-blood-biologics/qa-comirnaty-covid-19-vaccine-mrna, accessed September 10, 2021.

Addressed in the next slide

Terry Adirim has acted outside the scope of her authority and misquotes the FDA guidance linked in her memo (Comirnaty Q&A Page)

SCOPE OF AUTHORITY

According to 10 USC, §1107a. Emergency use products

(a) Waiver by the President.-(1) 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.**

How is Comirnaty (COVID-19 Vaccine, mRNA) related to the Pfizer-BioNTech COVID-19 Vaccine authorized for emergency use?

The FDA-approved Comirnaty (COVID-19 Vaccine, mRNA) and the FDA-emergency use authorized Pfizer-BioNTech COVID-19 Vaccine for individuals 12 years of age and older, when prepared according to their respective instructions for use, 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 vaccines.

https://www.fda.gov/vaccines-blood-biologics/qa-comirnaty-covid-19-vaccine-mrna

Adirim directs that the EUA doses ***SHOULD*** be used as if they are licensed.
This is a misrepresentation of FDA guidance that says They ***CAN*** be used as if the doses were the licensed vaccine. *The intent was to create a sense of obligation*.

The legal requirement of the "option to accept or refuse" the administration of an EUA product is inexplicably removed due to a **misreading and dependence** on a FDA Q&A page

Title 21 states that guidance documents are not *legally* binding, the Q&A page is not official guidance

This absolutely does *not* remove the tenets of 10 USC 1107a or 21 USC 360bbb-3

https://www.law.cornell.edu/cfr/text/21/10.115

https://armypubs.army.mil/epubs/DR_pubs/DR_a/pdf/web/r40_562.pdf

AR 40-562
DODI 6200.02

Chapter 8
Vaccines and Other Products Used Under Emergency Use Authorization

8–1. General
Under 21 USC 564 (The Food, Dru
or licensed by the FDA through th
as medical countermeasures to che
grants an EUA. This EUA authorit
and follow IND rules (see chap.

8–2. Criteria
In general, the FDA may grant a
a. The Secretary of Defense or
for a military emergency relating to a particular CBRN agent or threat.
b. The Secretary of DHHS declares an emergency based on the Secretary of Defense's determinati
c. The Secretary of DHHS determines—
(1) The vaccine or drug may be effective in diagnosing, treating, or preventing the disease or condition.
(2) The known and potential benefits of the vaccine or drug outweigh the known and potential risks.
(3) There is no adequate, approved, and available alternative medical countermeasure.
d. The duration of authorization corresponds to the duration of the emergency or significant potential for an emergency.

8–3. Refusal options
The FDA may decide that potential recipients of a drug under an EUA should have the option to refuse it. The President may waive this option for military personnel.

8–4. Health recordkeeping requirements for emergency use authorization products
All EUA vaccines or chemoprophylaxis products that are administered must be recorded in the individual's permanent health record and/or DOD-approved electronic ITS.

8–5. Information requirements for emergency use authorization products
Any recipient of an EUA vaccine or chemoprophylaxis product must receive the information (for example, briefing, individual counseling, information statements) required by the FDA-approved EUA. Full compliance with this requirement is critical.

8–6. Department of Defense requests for emergency use authorizations
Requests for possible EUAs for military purposes must be submitted to ASD (HA) for consideration.

8–7. Coordination
The Army, as the Executive Agent for the Immunization Program for Biological Warfare Defense, maintains a program office at the USAMMDA. This office oversees and coordinates EUA product use for force health protection.

https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/620002p.pdf

This does not give ASD(HA)
authority to remove
the option to refuse
It only allows for instruction for implementation
Waiver authority is left to the President

E3.2. Request for EUA. Upon or in anticipation of a declaration of emergency referred to in section E3.1, the ASD(HA) may request from the Commissioner of Food and Drugs an EUA for use of a medical countermeasure within the scope of the declaration of emergency. The request for EUA shall comply with requirements of section 564 of Reference (d) and other requirements of the FDA. Combatant Commanders, through the Chairman of the Joint Chiefs of Staff, and other heads of DoD Components may recommend to the ASD(HA) the submission of requests under this paragraph.

E3.3. Implementation of EUA. DoD Components using medical products under an EUA shall comply with all requirements 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).

E3.4. Request to the President to Waive an Option to Refuse. 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.

E3.4.1. Combatant Commanders, through the Chairman of the Joint Chiefs of Staff, and other heads of DoD Components may recommend to the Secretary of Defense, through the ASD(HA), that the Secretary request a Presidential waiver of an option to refuse administration of an EUA product.

E3.4.2. If the President waives an option to refuse, DoD Components shall comply with all other EUA requirements, including the requirement for information provided to recipients of the EUA product consistent with section 1107a(b) of Reference (e).

E3.5. Pre-EUA Planning. To the extent practicable, Combatant Commanders, through the Chairman of the Joint Chiefs of Staff, and other heads of DoD Components shall coordinate with the Secretary of the Army, as Lead Component, appropriate planning activities, including the development of draft EUA requests to the FDA. The Secretary of the Army shall coordinate with the CDC in the case of potential EUA products of interest to the CDC in anticipation of domestic or public health emergencies and, with the approval of the ASD(HA), with the FDA.

INTERCHANGEABLE PRODUCTS VS REFERENCE PRODUCTS

An Interchangeable Product is created from a Reference Product

A reference product is the single biological product, already approved by FDA, against which a proposed biosimilar product is compared. A reference product is approved based on, among other things, a full complement of safety and effectiveness data. A proposed biosimilar product is compared to and evaluated against a ***reference product*** to ensure that the product is highly similar and has no clinically meaningful differences.

A product can not be ***legally*** deemed interchangeable when there is no reference product.

Biologic Interchangeable Products are called “Biosimilars”

This means:

Both products ***must*** be FDA **approved**.
One cannot retain authorization while the other has approval.

Each biosimilar and each reference product are required to go through the entire approval process outlined in the Public Health Service Act Section 351(k) to be deemed interchangeable.

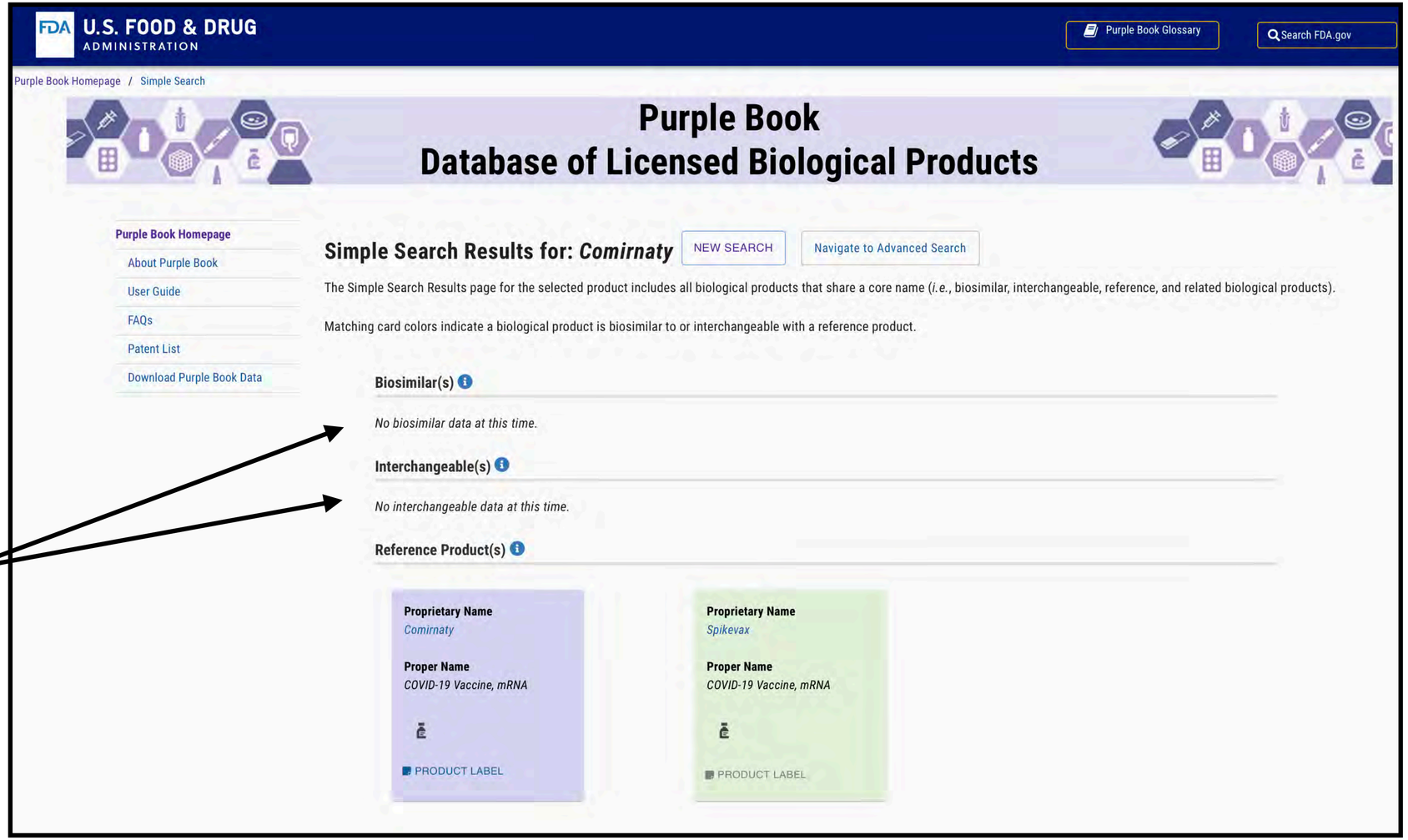
This is separate from Emergency Use Authorization, and they both have different statutory regulations.

https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products

FDA PurpleBook

This image is directly from the FDA'S PurpleBook Database

This clearly demonstrates that there is no legally or medically recognized interchangeable product



- *What did the FDA mean by saying the Pfizer-BioNtech Vaccine and Comirnaty can be used interchangeably but are legally distinct?*
- *How does FDA support their claim of interchangeability?*

https://purplebooksearch.fda.gov/results?query=COVID-19%20Vaccine,%20mRNA&title=Comirnaty

COVID-19 Vaccine (BNT162; PF-07302048)
Module 1.3.5.3 Exclusivity Claim

NOTICE OF CLAIMED EXCLUSIVITY

A. BioNTech Manufacturing GmbH hereby requests a determination that the licensure of Pfizer-BioNTech- COVID-19 constitutes the "first licensure" of Pfizer-BioNTech- COVID-19 and that BioNTech Manufacturing GmbH is entitled to exclusivity from the date of licensure pursuant to section 351(k)(7) of the Public Health Service Act.

B. There are no licensed biological products that are structurally related to Pfizer-BioNTech-COVID-19 for which BioNTech Manufacturing GmbH or one of its affiliates, licensors, predecessors in interest, or related entities are the current or previous license holders.

C. Accordingly, consistent with Section 351(k)(7)(C) of the Public Health Service Act, FDA's licensure of Pfizer-BioNTech- COVID-19 under 351(a) will constitute the "first licensure" of Pfizer-BioNTech- COVID-19.

1. Pursuant to Section 351(k)(7)(A), no approval of an application submitted under Section 351(k) for which Pfizer-BioNTech- COVID-19 is the reference product can be made effective until 12 years after the date of licensure of Pfizer-BioNTech-COVID-19.

2. Pursuant to Section 351(k)(7)(B), no application under Section 351(k) for which Pfizer-BioNTech- COVID-19 is the reference product can be submitted until 4 years after the date of licensure of Pfizer-BioNTech- COVID-19.

INTERCHANGEABLE PRODUCTS VS REFERENCE PRODUCTS Part 2

To sum up what this means, The Pfizer-BioNTech Vaccine is not eligible to be considered a legal interchangeable product as defined in the PHS Act

https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M1_exclusivity-claim.pdf

Properly Labeled Comirnaty and SpikeVax can be administered under Emergency Use Authorization (EUA) for indications not listed in the Biologics Licensing Application Approval if the conditions exist to justify an EUA

EUA

The argument that the EUA labeled product must remain available is deceptive and not factually accurate.

Each “EUA Indication” can be fulfilled by the proprietary products Comirnaty and SpikeVax

COMIRNATY and SPIKEVAX
are authorized for
uses not listed in the BLA

This would render the EUA labeled products unnecessary if the licensed product was available

[9] In the August 23, 2021 revision, FDA clarified that, subsequent to the FDA approval of COMIRNATY (COVID-19 Vaccine, mRNA) for the prevention of COVID-19 for individuals 16 years of age and older, this EUA would remain in place for the Pfizer-BioNTech COVID-19 Vaccine for the previously-authorized indication and uses. It also authorized COMIRNATY (COVID-19 Vaccine, mRNA) under this EUA for certain uses that are not included in the approved biologics license application (BLA). In addition, the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) was revised to provide updates on expiration dating of the authorized Pfizer-BioNTech COVID-19 Vaccine and updated language regarding warnings and precautions related to myocarditis and pericarditis. The Fact Sheet for Recipients and Caregivers was updated as the Vaccine Information Fact Sheet for Recipients and Caregivers, which comprises the F
BioNTech COVID-19 Vaccine and information about the FDA-licensed vacc
Vaccine, mRNA).

This authorization also covers the use of the licensed SPIKEVAX (COVID-19 Vaccine, mRNA) product when used to provide: (1) a third primary series dose (0.5 mL) at least 1 month following the second dose to individuals 18 years of age or older who have undergone solid organ transplantation or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise; (2) a single homologous booster dose (0.25 mL) at least 5 months after completion of the primary series to individuals 18 years of age or older; and (3) a single booster dose as a heterologous booster dose (0.25 mL) following completion of primary vaccination with another authorized or approved COVID-19 vaccine in individuals 18 years of age and older, where the dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination.

Therefore, for individuals 18 years of age and older, SPIKEVAX (COVID-19 Vaccine, mRNA) is authorized to complete the primary regimen or provide a booster dose for individuals who received their initial primary dose(s) with the Moderna COVID-19 Vaccine, and the Moderna COVID-19 Vaccine is authorized to complete the primary regimen or provide a booster for individuals who received their initial primary dose(s) with SPIKEVAX (COVID-19 Vaccine, mRNA).

[11] Although SPIKEVAX (COVID-19 Vaccine, mRNA) and Comirnaty (COVID-19 Vaccine, mRNA) are approved to prevent COVID-19 in certain individuals within the scope of the Moderna COVID-19 Vaccine authorization, there is not sufficient approved vaccine available for distribution to this population in its entirety at the time of reissuance of this EUA. Additionally, there are no COVID-19 vaccines that are approved to provide: a third primary series dose to certain immunocompromised populations described in this EUA; a homologous booster dose to the authorized population described in this EUA; or a heterologous booster dose following completion of primary vaccination with another authorized or approved COVID-19 vaccine.

The reauthorization letter for both the
Pfizer-BioNTech vaccine and the Moderna Covid 19 vaccine
Both acknowledge there is no licensed product

https://www.fda.gov/media/150386/download

https://www.fda.gov/media/144636/download

Comirnaty under EUA and/or BLA covers all of the same groups
Making the continuation of EUA labeled products null

Table 1. Comparison of Patient Populations Covered by the Pfizer-BioNTech EUA and Comirnaty BLA

Patient Population	Pfizer-BioNTech EUA		Comirnaty BLA
	Pfizer-BioNTech	Comirnaty	
Individuals 0 to 11	x	x	x
Individuals 12 to 15	√	√	x
Individuals 16 and older	√	x	√
Third dose for certain immunocompromised individuals	√	√	x
Single booster dose at least six months after completing the primary vaccination series for certain individuals determined to be at high risk for severe COVID-19	√	√	x

BLA V EUA

https://crsreports.congress.gov/product/pdf/R/R46913

[9] The licensed vaccine has the same formulation as the EUA-authorized vaccine and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns. The products are legally distinct with certain differences that do not impact safety or effectiveness.

January 31, 2022 LOA

LEGALLY DISTINCT

Why did FDA refer to Comirnaty and the Pfizer-BioNTech vaccine as "legally distinct"?

In the EUA, FDA states that the Comirnaty and Pfizer-BioNTech vaccines "are legally distinct with certain differences that do not impact safety or effectiveness."[87] While the Comirnaty and Pfizer-BioNTech vaccines have the same formulation, they are legally allowed to be marketed and used pursuant to different legal authorities.[88] Specifically, Comirnaty is licensed pursuant to a BLA issued under the PHS Act (42 U.S.C. §262).[89] The Pfizer-BioNTech vaccine is authorized for emergency use pursuant to the Federal Food, Drug, and Cosmetic (FD&C) Act (21 U.S.C. §360bbb-3).[90]

Each product must be manufactured, labeled, marketed, distributed, and administered in accordance with the requirements of the legal regime under which it was approved or authorized. These requirements may differ in a number of ways. For example, under the EUA, the Pfizer-BioNTech vaccine must be accompanied by fact sheets for the vaccine administrator and recipient informing them, among other things, of the product's emergency authorization, known and anticipated risks and benefits, and the right to decline the vaccine.[91] Comirnaty need not be accompanied by this information if it is being administered pursuant to the BLA rather than the EUA; instead, the PHS Act and other FDA regulatory labeling requirements apply.[92]

As another example, the Pfizer-BioNTech vaccine may be manufactured only at facilities identified and agreed upon in Pfizer's EUA request, must be distributed directly by Pfizer or through authorized distributors to emergency response stakeholders (as defined in the EUA) as directed by the U.S. government, and must be administered by vaccination providers (as defined in the EUA) only to individuals 12 years of age and older in accordance with the uses authorized by the EUA.[93] These limitations do not apply to Comirnaty vaccines manufactured and distributed pursuant to the BLA; instead, the PHS Act and FD&C Act requirements apply. Comirnaty may be manufactured only at facilities identified and approved in the BLA.[94]

A September 29, 2021 Congressional Report addresses what legally distinct means and what requirements must be met for licensure versus authorization

The same report also makes a note that for purposes of 1107a A presidential waiver is required to mandate an EUA product

[130] There are some exceptions, such as where particular statutory authorities (or, in the employment context, contractual requirements such as collective bargaining agreements) distinguish between authorized and approved vaccines. For example, the Department of Defense interprets Title 10, Section 1107a, of the *U.S. Code* to preclude a mandate for EUA vaccines unless the President issues a waiver. See *OLC Section 564 Opinion*, pp. 16-17.

https://crsreports.congress.gov/product/pdf/R/R46913

https://www.fda.gov/media/144636/download

On November 12, 2021 Judge Winsor made a determination that any Vaccine produced prior to August 23, 2021 is and remains an EUA product despite DoD claims of BLA Compliance

According to the Pfizer lot information from CDC,
The manufacture dates for the 7 original lots are prior to the approval date

One problem with this argument is that the DOD's guidance documents explicitly say only FDA-licensed COVID-19 vaccines are mandated. *See, e.g.*, ECF No. 1-3 at 2 (DOD mandate memorandum) ("Mandatory vaccination against COVID-19 will only use COVID-19 vaccines that receive full licensure from the

[FDA] in accordance with FDA-approved labeling and guidance."); *and* ECF No. 1-7 at 11 (Air Force guidance) ("Only an FDA-licensed vaccine may be mandated . . . ."). The plaintiffs present a facial challenge, ECF No. 33 at 10 ("Plaintiffs' claims are facial challenges to a generally applicable military regulation . . . ."), and on its face, the mandate does not require anyone to take an EUA vaccine.

apply. *Id.* at 65:1-6.[8]

The DOD's interpretation of § 1107a is unconvincing. For starters, FDA licensure does not retroactively apply to vials shipped before BLA approval. *See* 21 U.S.C. § 355(a) ("No person shall introduce . . . into interstate commerce any new drug, unless an approval of an application [for FDA licensure] *is effective* with respect to such drug." (emphasis added)). Thus, as a legal matter, vaccines sent before August 23—and vaccines produced after August 23 in unapproved facilities—remain "product[s] authorized for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act." § 1107a(a)(1).[9] Section 1107a's explicit cross-reference to the EUA provisions suggests a concern that drugs mandated for military personnel be actually BLA-approved, not merely chemically similar to a BLA-approved drug. And the distinction is more than mere labeling: to be BLA compliant, the drug must be produced at approved facilities, *see* ECF No. 1-4 at 2; 21 C.F.R. §§ 600.11, 600.20-.21, and there is no indication that all EUA-labeled

Case 3:21-cv-01211-AW-HTC

JUDICIAL OPINION

PART 2

EUA vaccine.

Notably, though, the plaintiffs have shown that the DOD is requiring injections from vials not labeled "Comirnaty." Indeed, defense counsel could not even say whether vaccines labeled "Comirnaty" exist at all. ECF No. 45 at 48:5-7. (Although the DOD's response said it had an adequate Comirnaty supply, it later clarified that it was mandating vaccines from EUA-labeled vials. *See id.* at 46:22-47:3.) In the DOD's view, this is fine because the contents of EUA-labeled vials are chemically identical to the contents of vials labeled "Comirnaty" (if there are any such vials). According to the DOD's argument, this means servicemembers are not required to accept "a *product* authorized for emergency use." 10 U.S.C. § 1107a(a)(1). Rather, the DOD argues that once the FDA licensed Comirnaty, all EUA-labeled vials essentially became Comirnaty, even if not so labeled. ECF No. 45 at 60:1-3. Thus, the DOD argues, the "product" injected is a chemical formulation

The argument that all vials marked for Emergency Use became Comirnaty after approval is a legal misconception

Labeling has statutory requirements for all biologics under the Public Health and Service Act

Emergency Use labels are a violation of these statutory requirements, and EUA products are regulated differently than licensed products

Judge Winsor acknowledges this in the foot note below
FDA does not have the authority to remove the provisions of 10 USC 1107a

Most notably, FDA cannot retroactively license any product manufactured before its approval date

[9] This distinction is the basis for the FDA's comment that the BLA-compliant vials and the EUA-compliant vials are "legally distinct," even though their chemical formulation is identical. *See* ECF No. 1-6 at 3 n.8. Thus, the DOD cannot rely on the FDA to find that the two drugs are legally identical for § 1107a purposes.

National Drug Code Directory

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Search Results: *'comirnaty'*

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CSV

Search Results for Comirnaty only yield
New Formulation/Tris Buffer codes
These were created after the 12/16/2021 Supplement Approval

Marketing Start Date 12/22/2021

Display 50 **records per page**

Search for text in the table:

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category
Comirnaty	0069-2025-10	.225 mg/2.25mL	INJECTION, SUSPENSION	INTRAMUSCULAR	BLA125742	Pfizer Laboratories Div Pfizer Inc	0069-2025	COVID-19 Vaccine, mRNA	TOZINAMERAN	VACCINE	12/22/2021	N/A	BLA
Comirnaty	0069-2025-25	.225 mg/2.25mL	INJECTION, SUSPENSION	INTRAMUSCULAR	BLA125742	Pfizer Laboratories Div Pfizer Inc	0069-2025	COVID-19 Vaccine, mRNA	TOZINAMERAN	VACCINE	12/22/2021	N/A	BLA

Showing 1 to 2 of 2 entries

Previous 1 Next

FDA still designates all of these NDC Codes as Emergency Use,
which means they are under the statutory regulations of that designation.
This furthers the question of misbranding and the claims of interchangeability that is not properly defined
FDA violates the statutory requirements for labeling and interchangeability laid out in the PHSA

Display 50 records per page

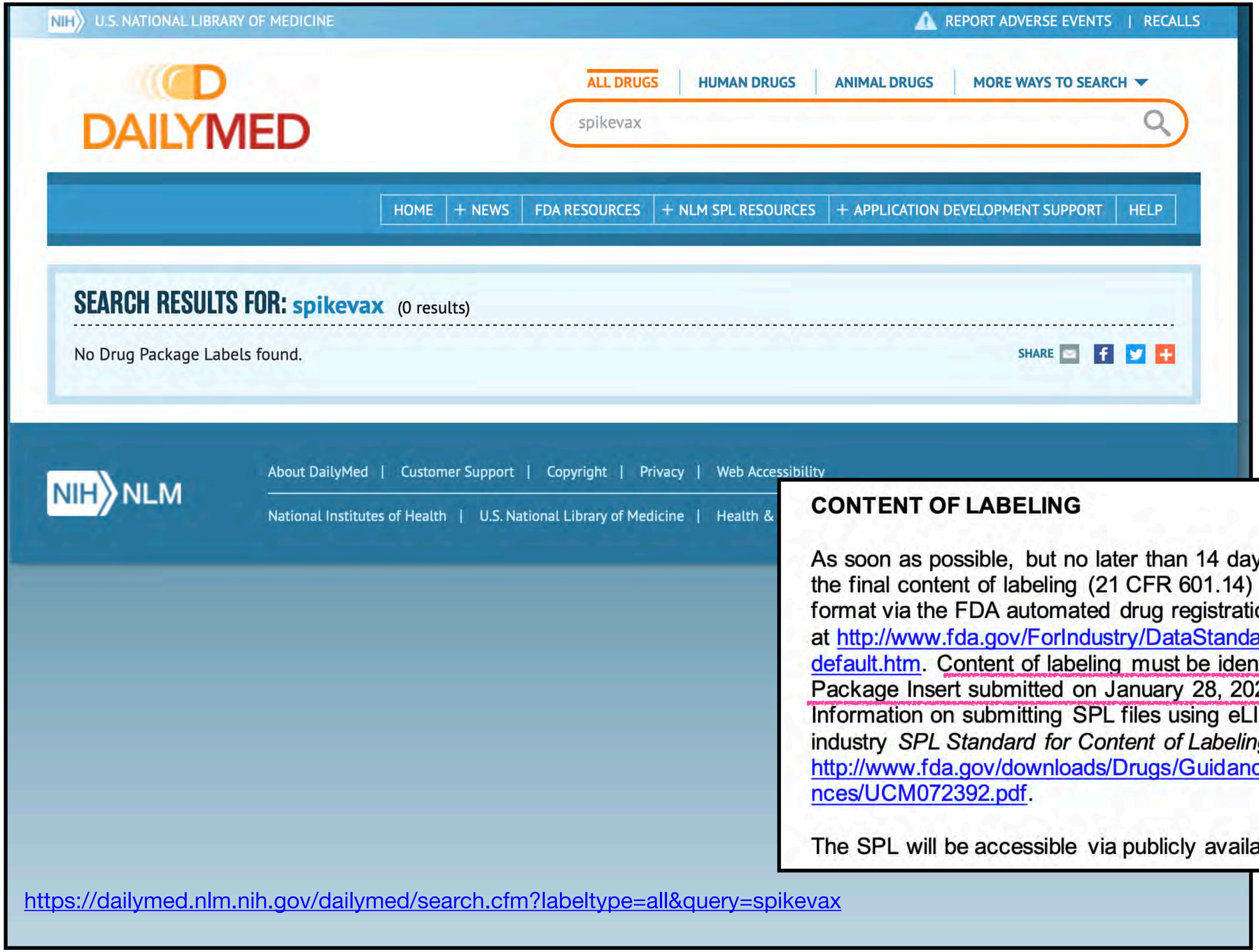
Search for text in the table:

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category
PENICILLIN G PROCAINE	60793-130-10	600000 [iU]/mL	INJECTION, SUSPENSION	INTRAMUSCULAR	ANDA060101	Pfizer Laboratories Div Pfizer Inc	60793-130	penicillin g procaine	PENICILLIN G PROCAINE	HUMAN PRESCRIPTION DRUG	04/26/1948	N/A	ANDA
PENICILLIN G PROCAINE	60793-131-10	1200000 [iU]/2mL	INJECTION, SUSPENSION	INTRAMUSCULAR	ANDA060101	Pfizer Laboratories Div Pfizer Inc	60793-131	penicillin g procaine	PENICILLIN G PROCAINE	HUMAN PRESCRIPTION DRUG	04/26/1948	N/A	ANDA
Pfizer-BioNTech Covid-19 Vaccine	59267-0078-2	3 ug/.2mL	INJECTION, SUSPENSION	INTRAMUSCULAR		Pfizer Manufacturing Belgium NV	59267-0078	BNT162b2	TOZINAMERAN	VACCINE	08/13/2021	N/A	EMERGENCY USE AUTHORIZATIO
Pfizer-BioNTech Covid-19 Vaccine	59267-0078-4	3 ug/.2mL	INJECTION, SUSPENSION	INTRAMUSCULAR		Pfizer Manufacturing Belgium NV	59267-0078	BNT162b2	TOZINAMERAN	VACCINE	08/13/2021	N/A	EMERGENCY USE AUTHORIZATIO
Pfizer-BioNTech Covid-19 Vaccine	59267-1000-2	.225 mg/2.25mL	INJECTION, SUSPENSION	INTRAMUSCULAR		Pfizer Manufacturing Belgium NV	59267-1000	BNT162b2	TOZINAMERAN	VACCINE	12/12/2020	N/A	EMERGENCY USE AUTHORIZATIO
Pfizer-BioNTech Covid-19 Vaccine	59267-1000-3	.225 mg/2.25mL	INJECTION, SUSPENSION	INTRAMUSCULAR		Pfizer Manufacturing Belgium NV	59267-1000	BNT162b2	TOZINAMERAN	VACCINE	12/12/2020	N/A	EMERGENCY USE AUTHORIZATIO
Pfizer-BioNTech Covid-19 Vaccine	59267-1025-3	.225 mg/2.25mL	INJECTION, SUSPENSION	INTRAMUSCULAR		Pfizer Manufacturing Belgium NV	59267-1025	BNT162b2	TOZINAMERAN	VACCINE	10/30/2021	N/A	EMERGENCY USE AUTHORIZATIO
Pfizer-BioNTech Covid-19 Vaccine	59267-1025-4	.225 mg/2.25mL	INJECTION, SUSPENSION	INTRAMUSCULAR		Pfizer Manufacturing Belgium NV	59267-1025	BNT162b2	TOZINAMERAN	VACCINE	10/30/2021	N/A	EMERGENCY USE AUTHORIZATIO
Pfizer-BioNTech Covid-19 Vaccine	59267-1055-4	130 ug/2.6mL	INJECTION, SUSPENSION	INTRAMUSCULAR		Pfizer Manufacturing Belgium NV	59267-1055	BNT162b2	TOZINAMERAN	VACCINE	10/30/2021	N/A	EMERGENCY USE AUTHORIZATIO

The FDA requirement for the Covid Vaccines under EUA must be accompanied by an EUA fact sheet

EUA CODES

DailyMed SpikeVax



https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=all&query=spikevax

SpikeVax is still unavailable,
And no labels have been published

SpikeVax approval letter labeling requirements

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the final content of labeling (21 CFR 601.14) in Structured Product Labeling (SPL) format via the FDA automated drug registration and listing system, (eLIST) as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the Package Insert and Patient Package Insert submitted on January 28, 2022 and December 16, 2021, respectively. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As* at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

https://www.fda.gov/media/155815/download

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Search Results: *'spikevax'*

Your search returned no records.

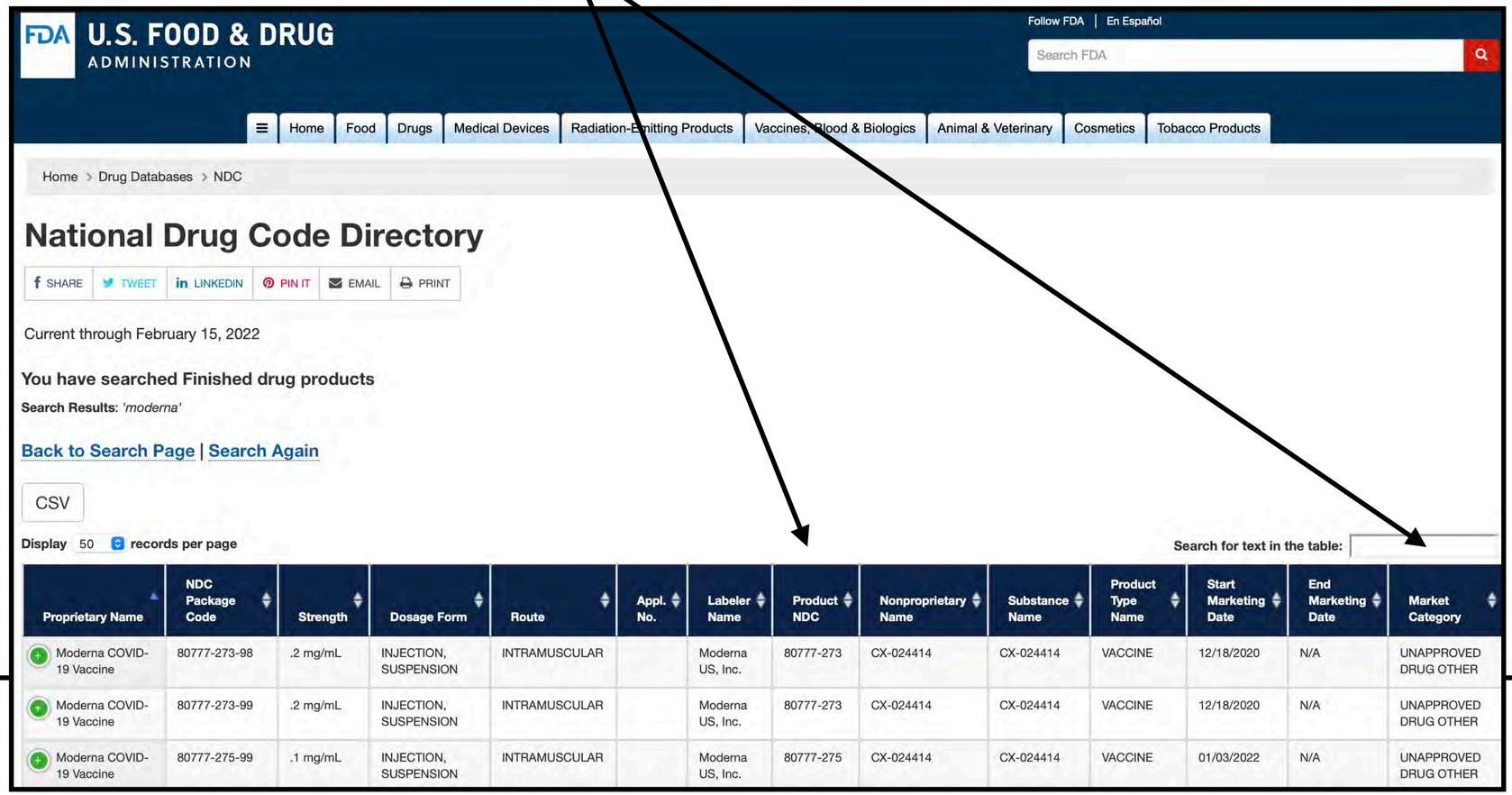
Background Information

Drug questions email: DRUGINFO@FDA.HHS.GOV

See also: Drug Registration and Listing Instructions
National Drug Code Directory Data Files

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

SpikeVax has not been published
The Covid 19 vaccine is Moderna's only published drug, and only has EUA codes

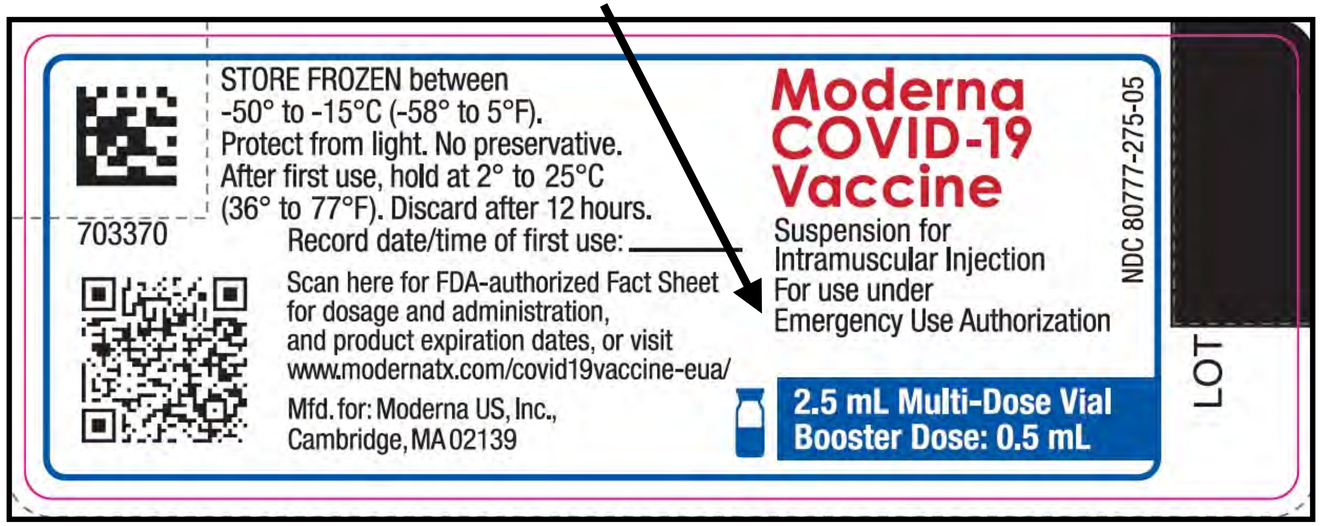


Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category
Moderna COVID-19 Vaccine	80777-273-98	.2 mg/mL	INJECTION, SUSPENSION	INTRAMUSCULAR		Moderna US, Inc.	80777-273	CX-024414	CX-024414	VACCINE	12/18/2020	N/A	UNAPPROVED DRUG OTHER
Moderna COVID-19 Vaccine	80777-273-99	.2 mg/mL	INJECTION, SUSPENSION	INTRAMUSCULAR		Moderna US, Inc.	80777-273	CX-024414	CX-024414	VACCINE	12/18/2020	N/A	UNAPPROVED DRUG OTHER
Moderna COVID-19 Vaccine	80777-275-99	.1 mg/mL	INJECTION, SUSPENSION	INTRAMUSCULAR		Moderna US, Inc.	80777-275	CX-024414	CX-024414	VACCINE	01/03/2022	N/A	UNAPPROVED DRUG OTHER

https://www.accessdata.fda.gov/scripts/cder/ndc/dsp_searchresult.cfm

MODERNA LABELS

Labels are still clearly marked for “Emergency Use”



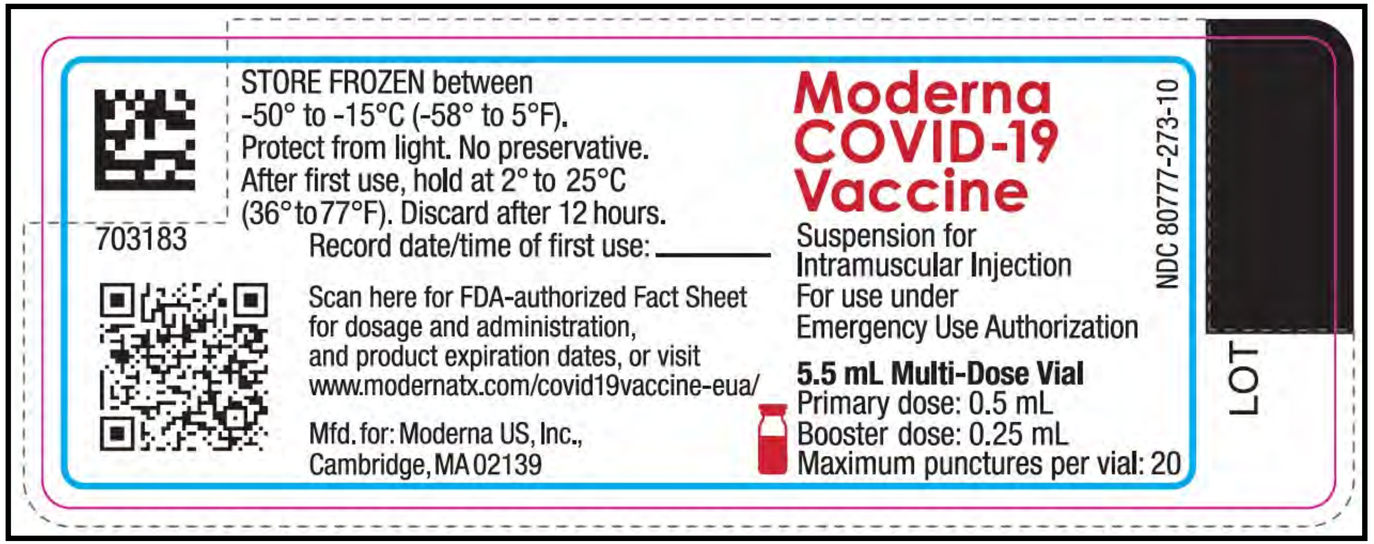
NDC CODES

MODERNA COVID-19 VACCINE- cx-024414 injection, suspension

If this SPL contains inactivated NDCs listed by the FDA initiated compliance action, they will be specified as such.

	NDC
1	80777-275-05
2	80777-275-99

CONT'D



NDC CODES

MODERNA COVID-19 VACCINE- cx-024414 injection, suspension

If this SPL contains inactivated NDCs listed by the FDA initiated compliance action, they will be specified as such.

	NDC
1	80777-273-10
2	80777-273-15
3	80777-273-98
4	80777-273-99

EUA Labels and Codes Part 2

Conclusion

The DoD does not have the properly licensed and labeled vaccine guaranteed by Secretary Austin's memo

All vaccines currently mandated remain under Emergency Use, and are a direct violation of 10 USC 1107a

Terry Adirim has acted outside her scope of authority, and did not adequately explain proper protocol for administering EUA doses to Service Members

FDA guidance referenced by Terry Adirim on interchangeability does not remove the right "to accept or refuse" an EUA product

The Public Health and Service Act clearly defines the regulations of biologics and interchangeable products

FDA has failed to meet this legal standard of "Interchangeable" and licensure for 10 USC 1107a purposes

Title 21 determines a product is misbranded if its NDC code is used to denote or imply approval
e.g. "BLA Compliant" or "BLA Approved" lots found in the Dear HCP letter

Prior to the approval of the Pfizer-BioNTech Vaccine, it was clear it was not maintaining efficacy and there were significant rises in breakthrough cases.
Making the Covid 19 Vaccine mandate for Service Members capricious and arbitrary

There is no policy to deny service members exemptions or any provisions listed in AR 40-562