# Mask and Test Kit Legal EUA Cross Walk

- "But the Secretary of HHS Did Not **Provide the Condition** to Accept/Refuse Masks for test kits/masks in the Fact Sheets (or in general)"
- "The FDA approved (legally Licensed) the test Test Kits or Masks/Test Kits so we can fully mandate this…closely related to "But the CDC said to do it"
- "Only Shots require informed consent or to be notified of the right to refuse"

**Bottom Line Up Front**: Masks and Test Kits are unapproved Emergency Use Authorized medical devices (which is a type of an EUA Product) and come with the inherent right to refuse (21 U.S.C. 360bbb-3(e)(1)(A)(ii)(I-III)). For DoD service members, there is also NO POTUS Waiver 10 U.S.C. § 1107a in writing which waives the right for Servicemembers to be informed of the right to refuse. EVEN a written POTUS Waiver CANNOT waive the actual RIGHT to Refuse.

- **We (all Americans) NEVER lose the right to REFUSE an EUA Product because EUA PRODUCTS are Unapproved (unlicensed)** writ large because the pandemic started due to a Public Health Emergency declaration because the SARS-COV-2 is a "novel" corona virus and we did not collectively have "approved (licensed)" products available to prevent, treat, cure, or diagnose SARS COV 2 or COVID19.
- A licensed product would have to undergo many years of intense safety/efficacy testing to be fully licensed, cleared, or certified for use by the FDA
- ALL test kits and masks come with inherent rights to refuse because
    - 1) they are unapproved EUA products and have REQUIRED statutory conditions in 21 U.S.C. 360bbb-3(e)(1)(A)(i-ii)…Right to refuse is found in 21 U.S.C. 360bbb-3 (e)(1)(A)(ii)(III)
    - 2) lack long-term studies for safety and efficacy and
    - 3) each EUA letter (which is the legally binding agreement between the US Government thru the FDA with the manufacturer) clearly states that test kits and masks **CANNOT** advertise to be safe or effective at diagnosing or preventing COVID19
    - 4) Each EUA Letter CLEARLY States The FDA grants manufacturers of test kits and masks a waiver to follow good manufacturing practices in accordance with 21 Code of Federal Regulations part 820…Means that the FDA waived the need to follow good, safe practices…further means YOU as the individual ACCEPT even MORE RISK, and
    - 5) EUA Letters CLEARLY STATES that these products must "conspicuously state they are not FDA approved or cleared to treat, prevent, diagnose, or cure COVID19".
- **The EUA Letters serve as the Legal agreement (binding)** between the FDA (US Government) and the Manufacturers. **USE EUA LETTERs as the basis for all of your supporting arguments along with the corresponding federal laws.**

- **FACT SHEETs are NOT legally binding** agreements between the government and are used for reference, but **NOT** used to serve as a binding agreement between the US Government/manufacturer. It is a guidance document done by staff officers or subject matter experts (meaning a manufacturer rep (covered person) helps the FDA (covered person) craft a document for medical providers/healthcare workers (covered persons) to tell Covered Persons (healthcare providers) how to use a manufacturers (covered person's) EUA products which become "covered counter measures."
    - Of note both entities in an EUA letter are considered "Covered Persons" and are immune from legal liability for any damages for using, administering, or recommending use of an EUA product under 42 U.S.C. § 247d-6d (Targeted Liability Protections for Covered Persons)

    - Put another way the "Covered Person" with legal liability (FDA) from any damage claims (from you) grants the "covered person" (manufacturer) the ability to produce products with less safety standards…because both are covered persons from legal liability under 42 U.S.C. § 247d-6d. So two parties with legal liability immunity to manufacture, sell, distribute an unlicensed, less safe (unapproved EUA Product) or "covered countermeasure" (EUA product for a qualified pandemic/endemic-COVID19) into the US Market. **This fact alone is why YOU have the right to refuse and why masks and test kits are indeed EUA products, come with the right to refuse which is NOT optional…but REQUIRED.**

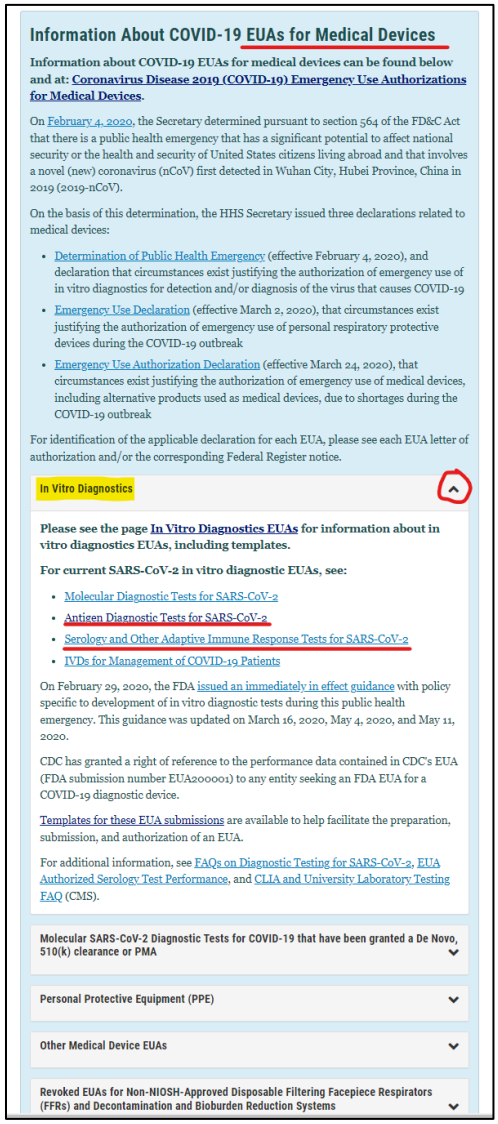
    - Each EUA letter allows the manufacturer to place a product (shot, mask, test kit, drugs) in the US market with complete legal immunity under 42 U.S.C. § 247d-6d.

# Beginning the Crosswalk

- There are two primary locations on the FDA page to locate In-Vitro Diagnostic Test Kits and Masks. You need to be able to locate both regularly
- (Test Kits)In Vitro Diagnostics EUAs - Antigen Diagnostic Tests for SARS-CoV-2 | FDA
- (Masks) Personal Protective Equipment EUAs | FDA

[TEST KITS] In Vitro Diagnostics EUAs - Antigen Diagnostic Tests for SARS-CoV-2 | FDA [EUA Letters for ALL 59 EUA Test Kits] Click Link, scroll down to see the picture below:

We are mostly familiar with receiving RAPID Antigen Tests and PCR Tests. All of these diagnostic test kits are classified as In-Vitro Test Kits and are medical Devices



**Information About COVID-19 EUAs for Medical Devices**

**Information about COVID-19 EUAs for medical devices can be found below and at: Coronavirus Disease 2019 (COVID-19) Emergency Use Authorizations for Medical Devices.**

On February 4, 2020, the Secretary determined pursuant to section 564 of the FD&C Act that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves a novel (new) coronavirus (nCoV) first detected in Wuhan City, Hubei Province, China in 2019 (2019-nCoV).

On the basis of this determination, the HHS Secretary issued three declarations related to medical devices:

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**In Vitro Diagnostics**

**Please see the page In Vitro Diagnostics EUAs for information about in vitro diagnostics EUAs, including templates.**

**For current SARS-CoV-2 in vitro diagnostic EUAs, see:**

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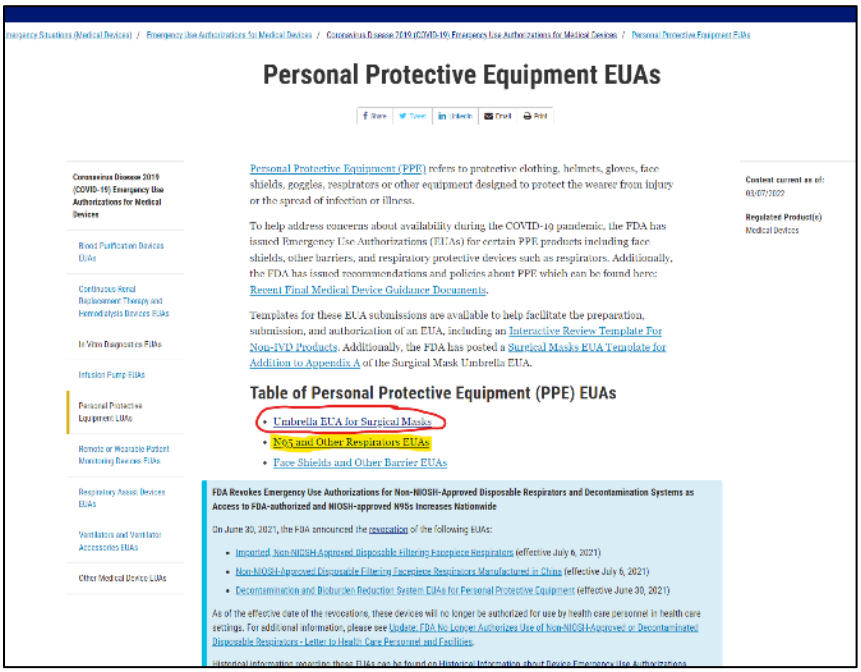
**Personal Protective Equipment (PPE)**

**Other Medical Device EUAs**

**Revoked EUAs for Non-NIOSH-Approved Disposable Filtering Facepiece Respirators (FFRs) and Decontamination and Bioburden Reduction Systems**

[Personal Protective Equipment EUAs | FDA](#) (MASKS)

We all are familiar with Masks



Personal Protective Equipment EUAs

Coronavirus Disease 2019 (COVID-19) Emergency Use Authorizations for Medical Devices

Blood Purification Devices EUAs

Continuous Renal Replacement Therapy and Hemodialysis Devices EUAs

In Vitro Diagnostics EUAs

Infusion Pump EUAs

Personal Protective Equipment EUAs

Remote or Wearable Patient Monitoring Devices EUAs

Respiratory Assist Devices EUAs

Ventilators and Ventilator Accessories EUAs

Other Medical Device EUAs

Personal Protective Equipment (PPE) refers to protective clothing, helmets, gloves, face shields, goggles, respirators or other equipment designed to protect the wearer from injury or the spread of infection or illness.

To help address concerns about availability during the COVID-19 pandemic, the FDA has issued Emergency Use Authorizations (EUAs) for certain PPE products including face shields, other barriers, and respiratory protective devices such as respirators. Additionally, the FDA has issued recommendations and policies about PPE which can be found here: Recent Final Medical Device Guidance Documents.

Templates for these EUA submissions are available to help facilitate the preparation, submission, and authorization of an EUA, including an Interactive Review Template For Non-IVD Products. Additionally, the FDA has posted a Surgical Masks EUA Template for Addition to Appendix A of the Surgical Mask Umbrella EUA.

Table of Personal Protective Equipment (PPE) EUAs

- Umbrella EUA for Surgical Masks
- N95 and Other Respirators EUAs
- Face Shields and Other Barrier EUAs

FDA Revokes Emergency Use Authorizations for Non-NIOSH-Approved Disposable Respirators and Decontamination Systems as Access to FDA-authorized and NIOSH-approved N95s Increases Nationwide

On June 30, 2021, the FDA announced the revocation of the following EUAs:

- Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators (effective July 6, 2021)
- Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China (effective July 6, 2021)
- Decontamination and Bioburden Reduction System EUAs for Personal Protective Equipment (effective June 30, 2021)

As of the effective date of the revocations, these devices will no longer be authorized for use by health care personnel in health care settings. For additional information, please see Update: FDA No Longer Authorizes Use of Non-NIOSH-Approved or Decontaminated Disposable Respirators - Letter to Health Care Personnel and Facilities.

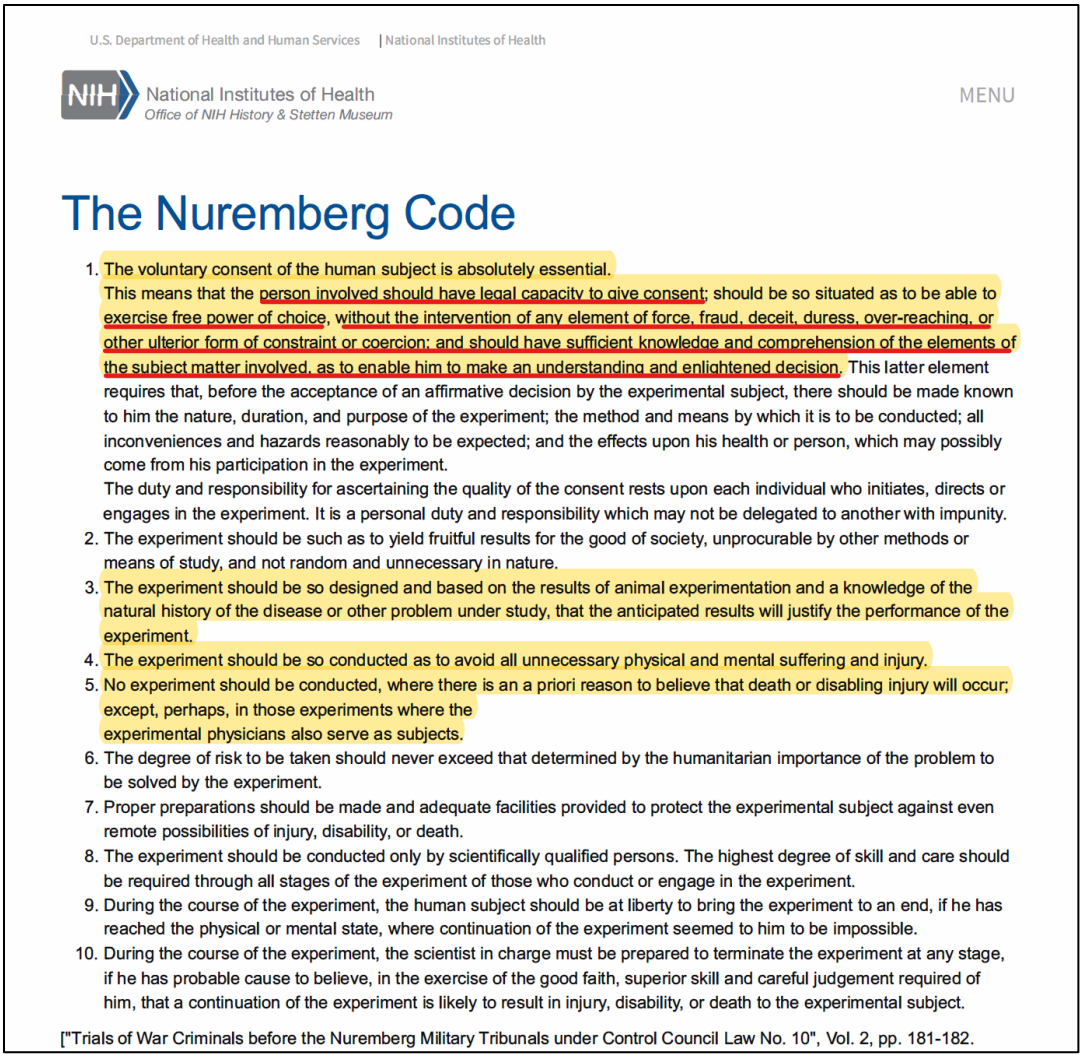
Content current as of: 03/07/2022

Regulated Product(s): Medical Devices

## How to Crosswalk this Argument.

1. Start with the Legal References and definitions. Read it/print it/have your leadership read it **word.for.word with leaders** too. If you READ directly from the laws, it avoids you paraphrasing or sounding like you are stating an unqualified opinion. The goal is to instruct most on these laws, because many do not know the laws or where to find this information.

A. Nuremberg Code. Key points to hit are in the top (No 1.) and these points became inextricably woven into 21 U.S.C. § 360bbb-3. These principles became part of US federal laws and are designed to protect Americans from what humanity said is fundamentally wrong:



U.S. Department of Health and Human Services | National Institutes of Health

National Institutes of Health
*Office of NIH History & Stetten Museum*

MENU

# The Nuremberg Code

1. The voluntary consent of the human subject is absolutely essential.
   This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him to make an understanding and enlightened decision. This latter element requires that, before the acceptance of an affirmative decision by the experimental subject, there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person, which may possibly come from his participation in the experiment.
   The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.
2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study, that the anticipated results will justify the performance of the experiment.
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted, where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
9. During the course of the experiment, the human subject should be at liberty to bring the experiment to an end, if he has reached the physical or mental state, where continuation of the experiment seemed to him to be impossible.
10. During the course of the experiment, the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgement required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

["Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10", Vol. 2, pp. 181-182.

B. Define what Laws Govern Emergency Use Products for Americans (and service members) In short 21 U.S.C. § 360bbb-3, 42 U.S.C. § 247d-6d, and 10 U.S.C. 1107a

21 U.S.C. § 360bbb-3(a)(2)(A). Masks and Test Kits both fall under (A) because they are unapproved, licensed, or cleared and all Emergency Use Authorization Letters, the boxes, the packaging, and device inserts (for test kits) must “conspicuously” state these products are unapproved/cleared/licensed.

- Define Medical Product and show that a “Product” encompasses test kits and masks because both are **medical devices** (21 U.S.C. § 321).
- Masks and Test Kits are definitely not approved and are a medical device
- They are legally eligible for the FDA to grant an EUA since at present there are no licensed (approved) devices to treat, cure, prevent, or diagnose COVID19

**§360bbb–3. Authorization for medical products for use in emergencies**

**(a) In general**

**(1) Emergency uses**

Notwithstanding any provision of this chapter and section 351 of the Public Health Service Act [42 U.S.C. 262], and subject to the provisions of t
a declaration under subsection (b), of a drug, device, or biological product intended for use in an actual or potential emergency (referred to in this s

**(2) Approval status of product**

An authorization under paragraph (1) may authorize an emergency use of a product that-

(A) is not approved, licensed, or cleared for commercial distribution under section 355, 360(k), 360b, or 360e of this title or section 351 of the
in this section as an "unapproved product"); or

(B) is approved, conditionally approved under section 360ccc of this title, licensed, or cleared under such a provision, but which use is not unc
of the product (referred to in this section as an "unapproved use of an approved product").

**(3) Relation to other uses**

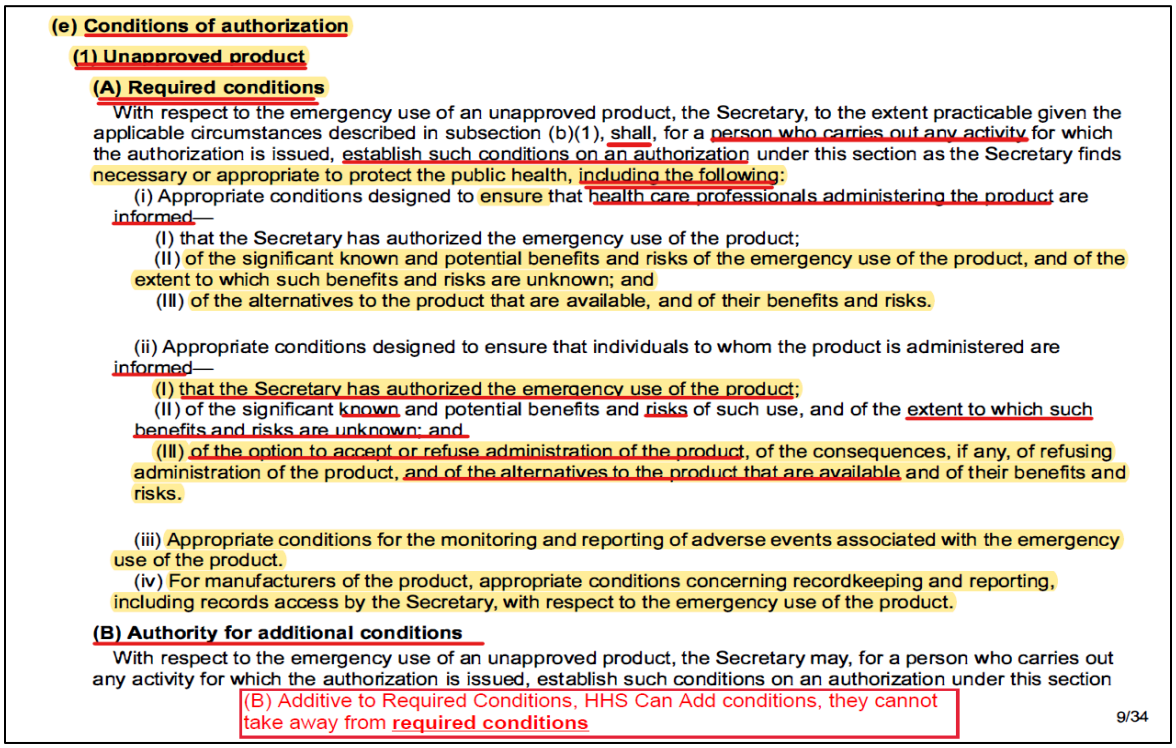
An emergency use authorized under paragraph (1) for a product is in addition to any other use that is authorized for the product under a section

**(4) Definitions**

For purposes of this section:

(A) The term "biological product" has the meaning given such term in section 351 of the Public Health Service Act [42 U.S.C. 262].
(B) The term "emergency use" has the meaning indicated for such term in paragraph (1).
(C) The term "product" means a drug, device, or biological product.
(D) The term "unapproved product" has the meaning indicated for such term in paragraph (2)(A).
(E) The term "unapproved use of an approved product" has the meaning indicated for such term in paragraph (2)(B).

21 U.S.C. § 360bbb-3 (e)(1)(A): UNAPPROVED PRODUCTS. Demonstrate that because products are unapproved and thereforce unlicensed, they come with **REQUIRED CONDITIONS** (legal package deal that is directive and not suggestive; must/shall do versus should/may/could do)



**(e) Conditions of authorization**

**(1) Unapproved product**

**(A) Required conditions**

With respect to the emergency use of an unapproved product, the Secretary, to the extent practicable given the applicable circumstances described in subsection (b)(1), shall, for a person who carries out any activity for which the authorization is issued, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including the following:

(i) Appropriate conditions designed to ensure that health care professionals administering the product are informed—

(I) that the Secretary has authorized the emergency use of the product;

(II) of the significant known and potential benefits and risks of the emergency use of the product, and of the extent to which such benefits and risks are unknown; and

(III) of the alternatives to the product that are available, and of their benefits and risks.

(ii) Appropriate conditions designed to ensure that individuals to whom the product is administered are informed—

(I) that the Secretary has authorized the emergency use of the product;

(II) of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and

(III) of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.

(iii) Appropriate conditions for the monitoring and reporting of adverse events associated with the emergency use of the product.

(iv) For manufacturers of the product, appropriate conditions concerning recordkeeping and reporting, including records access by the Secretary, with respect to the emergency use of the product.

**(B) Authority for additional conditions**

With respect to the emergency use of an unapproved product, the Secretary may, for a person who carries out any activity for which the authorization is issued, establish such conditions on an authorization under this section

(B) Additive to Required Conditions, HHS Can Add conditions, they cannot take away from **required conditions**

9/34

C. 10 U.S.C. § 1107a (Emergency Use Products) What does the DoD say and how do we define EUA products?

-Key Points:

The DoD Follows the legal definitions of EUA products established in 21 U.S.C. 360bbb-3(a)(4).

The DoD cannot sub-define or set forth what products are or are NOT EUA products.

10 U.S.C. § 1107a is titled **Emergency Use Products** and **does NOT** distinguish that this section only pertains to a certain class or group of products. 1107a is ALL encompassing for EUA Products as defined in in 21 U.S.C. 360bbb-3(a)(4). So, if the FDA/HHS grants an emergency use authorization for a product, then 10 U.S.C. § 1107a applies to ALL EUA Products (shots, test kits/masks, drugs, PPE).

## §1107a. Emergency use products

Products (biological products-shots, devices-test kits/masks/PPE, and drugs-pills/injectables

(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. The Written POTUS waiver ONLY waives the required condition that Service Members MUST be informed. Pay attention to the legal definition. We NEVER LOSE the RIGHT to REFUSE, only to be informed if POTUS Waives this required condition in writing. 21 USC 360bbb-3 (e) (1) (A) (ii) (III) also states Americans MUST be INFORMED of the RIGHT to Accept/Refuse. BLUF: Service members and AMERICANS never lose our right to refuse legally!

(2) The waiver authority provided in paragraph (1) shall not be construed to apply to any case other than a case in which an individual is required to be informed of an option to accept or refuse administration of a particular product by reason of a determination by the Secretary of Health and Human Services that emergency use of such product is authorized under section 564 of the Federal Food, Drug, and Cosmetic Act.

(b) PROVISION OF INFORMATION.-If the President, under subsection (a), waives the condition described in section 564(e)(1)(A)(ii)(III) of the Federal Food, Drug, and Cosmetic Act, and if the Secretary of Defense, in consultation with the Secretary of Health and Human Services, makes a determination that it is not feasible based on time limitations for the information described in section 564(e)(1)(A)(ii)(I) or (II) of such Act and required under paragraph (1)(A) or (2)(A) of such section 564(e), to be provided to a member of the armed forces prior to the administration of the product, such information shall be provided to such member of the armed forces (or next-of-kin in the case of the death of a member) to whom the product was administered as soon as possible, but not later than 30 days, after such administration. The authority provided for in this subsection may not be delegated. Information concerning the administration of the product shall be recorded in the medical record of the member.

(c) APPLICABILITY OF OTHER PROVISIONS.-In the case of an authorization by the Secretary of Health and Human Services under section 564(a)(1) of the Federal Food, Drug, and Cosmetic Act based on a determination by the Secretary of Defense under section 564(b)(1)(B) of such Act, subsections (a) through (f) of section 1107 shall not apply to the use of a product that is the subject of such authorization, within the scope of such authorization and while such authorization is effective.

C. What is a Medical Device (21 U.S.C. § 321)?

(h)(1) The term "device" (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is-

(A) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

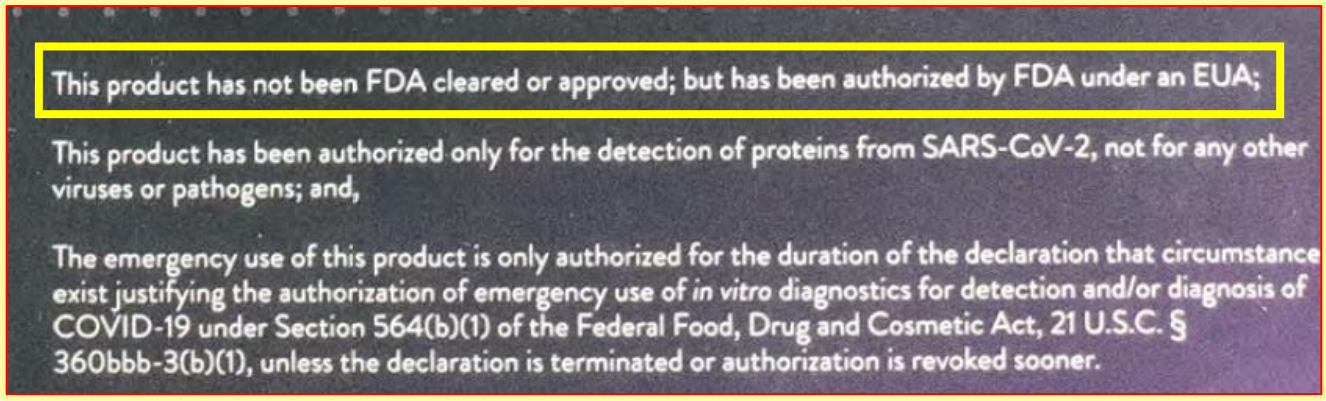
(B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(C) intended to affect the structure or any function of the body of man or other animals, and

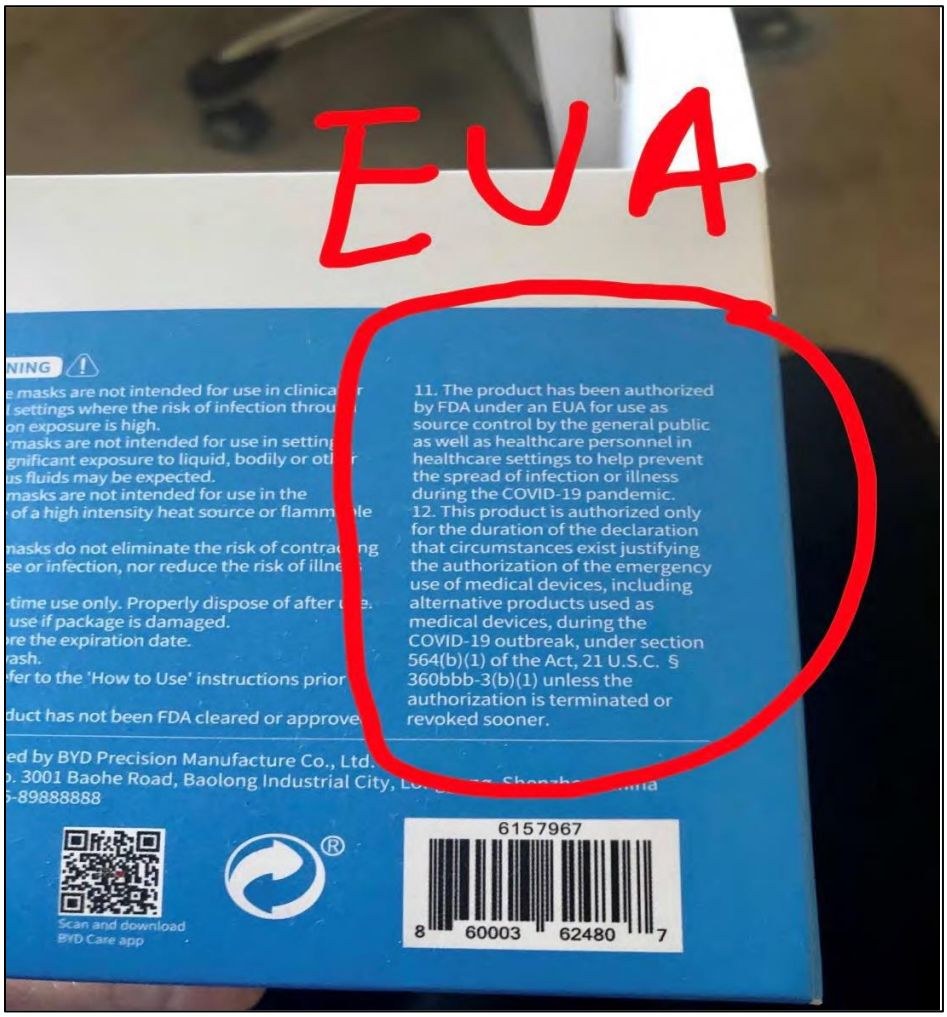
which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term "device" does not include software functions excluded pursuant to section 360j(o) of this title.

2. Take Pictures or find Boxes/Test Kits on your respective area or at a testing facility. Request the Box Inserts. Have both physically available or have multiple pictures available. (SHOW AND TELL TIME)

**FRONT** **BACK**


BYD CARE
BYD
Single-Use, General Purpose
Face Mask
Soft and easy to breathe
Non-Sterile
50 masks
3-Layer Flat Mask
Dimensions: 175mm×95mm / 6.89in.×3.74in.


EUA
11. The product has been authorized by FDA under an EUA for use as source control by the general public as well as healthcare personnel in healthcare settings to help prevent the spread of infection or illness during the COVID-19 pandemic.
12. This product is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices, including alternative products used as medical devices, during the COVID-19 outbreak, under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1) unless the authorization is terminated or revoked sooner.
Scan and download BYD Care app
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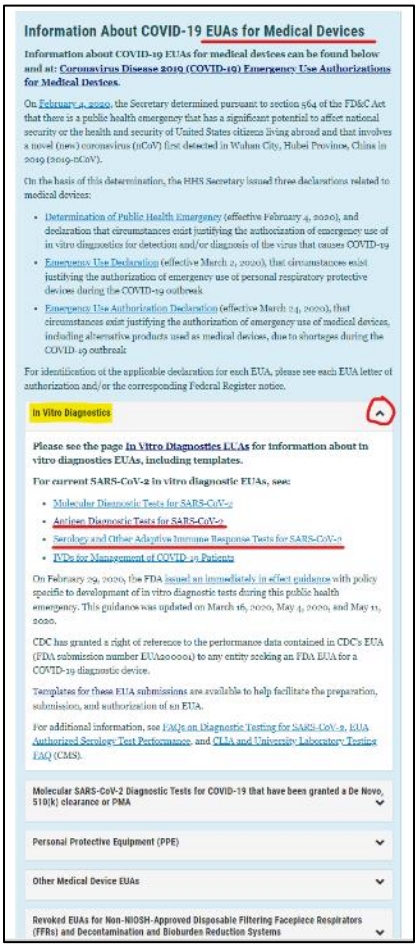
3. Locate/print/save the links to the respective EUA Letters on the FDA website [In Vitro Diagnostics EUAs - Antigen Diagnostic Tests for SARS-CoV-2 | FDA], **print this out!** EUA letters are the legally binding agreement between the FDA (US Government…and a Covered Person under 42 U.S.C. § 247d-6d) and the manufacturer (also a covered person from legal liability immunity under [42 U.S.C. § 247d-6d]

- SEC HHS MUST post EUA NOTICES to the Federal Register to highlight additions and revocations as required by 21 U.S.C. § 360bbb-3(h)
- 21 USC § 360bbb-3(h) states:

> **(h) Publication; confidential information**
>
> **(1) Publication**
>
> The Secretary shall promptly publish in the Federal Register a notice of each authorization, and each termination or revocation of an authorization under this section, and an explanation of the reasons therefor (which may include a summary of data or information that has been submitted to the Secretary in an application under section 355(i) [1] 360b(j), or 360j(g) of this title, even if such summary may indirectly reveal the existence of such application). The Secretary shall make any revisions to an authorization under this section available on the Internet Web site of the Food and Drug Administration.

A. Go to FDA EUA Link for Test Kits: [In Vitro Diagnostics EUAs - Antigen Diagnostic Tests for SARS-CoV-2 | FDA]



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**Revoked EUAs for Non-NIOSH-Approved Disposable Filtering Facepiece Respirators (FFRs) and Decontamination and Bioburden Reduction Systems**

# Individual EUAs for Antigen Diagnostic Tests for SARS-CoV-2

This table includes information about authorized SARS-CoV-2 antigen diagnostic tests that have been authorized individually. These EUAs have been issued for each individual test with certain conditions of authorization required of the manufacturer and authorized laboratories. Test attributes are listed in the "Attributes" column. For example, tests authorized for the screening of asymptomatic individuals without known exposure are listed with "screening" in the attribute column; pooling, multi-analyte, saliva, home collection, and home testing are similarly listed. Tests available without a prescription include the attribute "DTC" (for direct-to-consumer home collection tests) or "OTC" (for over-the-counter at-home tests).

For information on tests that have been revoked see Historical Information about Device Emergency Use Authorizations: In Vitro Diagnostics (IVD)

Tests with "single target" in the attribute column are:

- designed to detect only one antigen target, currently either a section of the spike protein or a section of the nucleocapsid protein;
- more susceptible to changes in performance due to viral mutations, meaning they are more likely to fail to detect new variants.

Tests with "multiple targets" in the attribute column are:

- designed to detect more than one section of the proteins that make up SARS-CoV-2;
- more likely to continue to perform as labeled as new variants emerge.

To see additional authorization documents, such as letters granting EUA amendments or revisions, and a list of other brand names authorized under a specific EUA, select the plus (+) button beside the "Date EUA Issued or Last Updated" for each EUA.

Authorized EUA devices in the table below for SARS-CoV-2 antigen diagnostic tests are assigned the QKP product code. Antigen multi-analyte respiratory panel tests authorized in the table below are assigned the QMN product code.

Search: Binax

Show 25 entries

| Date EUA Issued or Last Updated | Entity | Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued | Attributes | Authorized Setting(s)[1] | Authorization Documents[2] |
|---|---|---|---|---|---|
| 05/06/2022 | Abbott Diagnostics Scarborough, Inc. | BinaxNOW COVID-19 Ag Card Home Test 12/16/2020 | Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Telehealth Proctor Supervised, Serial Screening, Single Target | Home, H, M, W | HCP, Individuals, IFU, IFU (Home Test) |

THERE ARE 59 LISTED EUA LETTERS/TEST KITS on THIS SITE

BINAX NOW EUA LETTER (EXCERPTS) (CONSISTENT WITH ALL OTHER 59xIn-Vitro EUA TEST KITS)
--Follow the same procedures above to review other Test Kit EUA Letters.

U.S. FOOD & DRUG ADMINISTRATION

February 4, 2022

Angela Drysdale
VP, Regulatory Affairs
Abbott Diagnostics Scarborough, Inc.
10 Southgate Road
Scarborough, ME 04074

| | |
|---|---|
| Device: | BinaxNOW COVID-19 Ag 2 Card |
| EUA Number: | EUA210275 |
| Company: | Abbott Diagnostics Scarborough, Inc. |
| Indication: | Non-prescription use for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 with:<br>Direct anterior nasal (nares) swab samples from individuals with symptoms of COVID-19 within the first seven days of symptom onset.<br>Direct anterior nasal (nares) swab samples from individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 when test tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.<br>Emergency use of this test is limited to authorized laboratories. |
| Authorized Laboratories: | Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C 263a, that meet the requirements to perform moderate, high or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. |

Dear Ms. Drysdale:

On March 31, 2021, based on your[1] request the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of the BinaxNOW COVID-19 Ag 2 Card, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3) for the indications stated in the letter.[2] In addition, FDA established

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Abbott Diagnostics Scarborough, Inc.
[2] The March 31, 2021, letter authorized the BinaxNOW COVID-19 Ag 2 Card for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in direct anterior nasal (nares) swab samples from COVID-19 symptomatic individuals tested twice over three days with at least 36 hours between tests within the first seven days

FDA considered the totality of scientific information available in authorizing the emergency use of your product for the indication above. A summary of the performance information FDA relied upon is included in the Instructions for Use (identified below).

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of your product, described in the Scope of Authorization of this letter (Section II), subject to the terms of this authorization.

**I. Criteria for Issuance of Authorization**

I have concluded that the emergency use of your product meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. The SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in diagnosing COVID-19, and that the known and potential benefits of your product when used for diagnosing COVID-19, outweigh the known and potential risks of your product; and

3. There is no adequate, approved, and available alternative to the emergency use of your product.[8]

**II. Scope of Authorization**

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the indication above.

**Authorized Product Details**

Your product is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2. This test is authorized for non-prescription use with direct anterior nasal (nares) swab samples from individuals with symptoms of COVID-19 within the first seven days of symptom onset. This test is also authorized for non-prescription use with direct anterior nasal (nares) swab samples from individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 when test tested twice over three days with at least 24 hours (and no more than 48 hours) between tests. The BinaxNOW COVID-19 Ag 2 Card does not differentiate between SARS-CoV and SARS-CoV-2.

The SARS-CoV-2 nucleocapsid protein antigen is generally detectable in anterior nasal (nares) swabs during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with

[8] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

other viruses.

Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and presence of clinical signs and symptoms consistent with COVID-19.

For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of COVID-19, such as, an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

Imagine if other tests such as pregnancy, breathalizers, and cancer tests worked the same way? **For example, if you test negative for cancer do we give you Chemo anyways because you could in fact be positive?**

Negative results do not rule out infection? And positive results still "May" need to be double-checked.

Interesting prospect about efficacy.

l (nares) swab specimens using your product, as outlined in the
9 Ag 2 CARD," Instructions for Use, is limited to laboratories certified
ne requirements to perform high, moderate, or waived complexity tests.
or use at the POC, i.e., in patient care settings operating under a CLIA
ertificate of Compliance, or Certificate of Accreditation.

ct, the medical professional or trained operator performing the test must
ided in the "BinaxNOW COVID-19 Ag 2 CARD," Instructions for Use
OVID-19 Ag 2 CARD Procedure Card" when collecting the specimen,
re and interpreting the results.

The BinaxNOW COVID-19 Ag 2 Card includes the materials or other authorized materials (as may be requested under Condition N. below), required to collection the anterior nasal (nares) sample and perform the test procedure, as described in the "BinaxNOW COVID-19 Ag 2 CARD," Instructions for Use and the "BinaxNOW COVID-19 Ag 2 CARD Procedure Card."

Your product requires use of the Positive Control Swab and Negative Control Swab or other authorized controls (refer to Condition N. below), that are run as outlined in the Instructions for Use. Your product also requires the use of additional authorized materials and authorized ancillary reagents that are not included with your product and are described in the Instructions for Use.

The labeling entitled "BinaxNOW COVID-19 Ag 2 CARD" Instructions for Use and the

- Fact Sheet for Patients: Abbott Diagnostics Scarborough, Inc.- BinaxNOW COVID-19 Ag 2 Card

The above described product, when accompanied by the authorized labeling provided as set forth in the Conditions of Authorization (Section IV), is authorized to be distributed to and used by authorized laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of your authorized product, when used consistent with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of your product.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that your product may be effective in diagnosing COVID-19, when used consistent with the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that your product (as described in the Scope of Authorization of this letter (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of your product under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) of the Act described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1) of the Act, your product is authorized for the indication above.

**III. Waiver of Certain Requirements**

I am waiving the following requirements for your product during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of your product, but excluding Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

**IV. Conditions of Authorization**

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

deviations from the established performance characteristics of your product of which they become aware.

Z. All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.

**Abbott Diagnostics Scarborough, Inc. (You), Authorized Distributor(s) and Authorized Laboratories**

AA. You, authorized distributor(s), and authorized laboratories using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

**Conditions Related to Printed Materials, Advertising and Promotion**

BB. All descriptive printed matter, advertising, and promotional materials relating to the use of your product shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and meet the requirements set forth in section 502(a), (q)(1), and (r) of the Act, as applicable, and FDA implementing regulations.

CC. No descriptive printed matter, advertising, or promotional materials relating to the use of your product may represent or suggest that this test is safe or effective for the detection of SARS-CoV-2.

DD. All descriptive printed matter, advertising, and promotional materials relating to the use of your product shall clearly and conspicuously state that:

- This product has not been FDA cleared or approved; but has been authorized by FDA under an EUA for use by authorized laboratories;
- This product has been authorized only for the detection of proteins from SARS- CoV-2, not for any other viruses or pathogens; and,
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

The emergency use of your product as described in this letter of authorization must comply with the condition

**V. Duration of Authoriz**

**FRONT** **BACK**


This product has not been FDA cleared or approved; but has been authorized by FDA under an EUA;

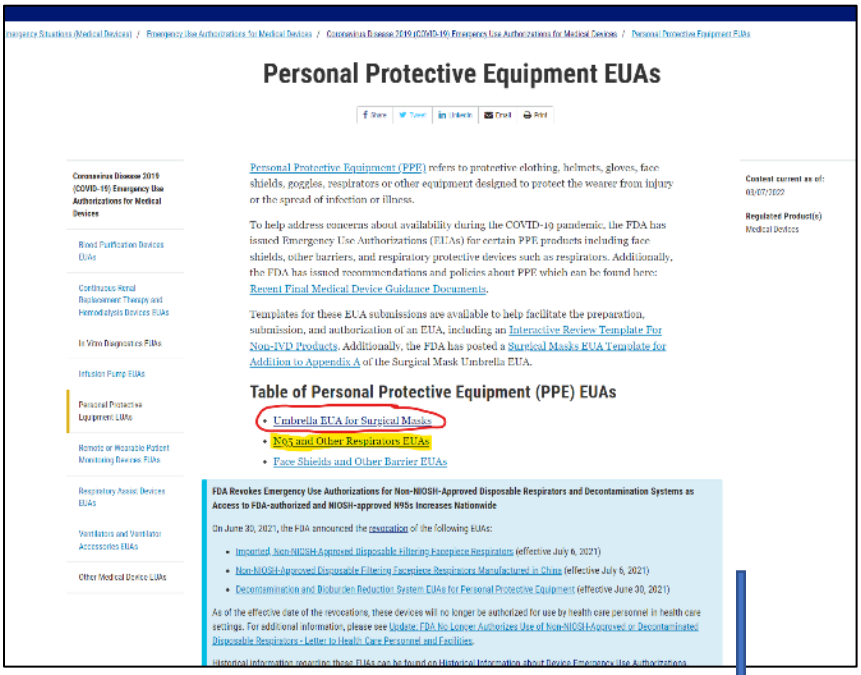
This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and,

The emergency use of this product is only authorized for the duration of the declaration that circumstance exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

**MASKS.** This section focuses on Surgical Masks. There are not discernable EUA Letters for Cloth Masks, which means that Cloth Masks typically will state “Not a Medical” Device on the package or Box. SO WHAT: If cloth masks are stating it is not a medical device, this covers a manufacturer from liability because we are USING a cloth mask for something OTHER THAN what it was intended to do (which is prevent spread of COVID19).

N95 Masks are also under an EUA.

Personal Protective Equipment EUAs | FDA (MASKS)



Personal Protective Equipment EUAs

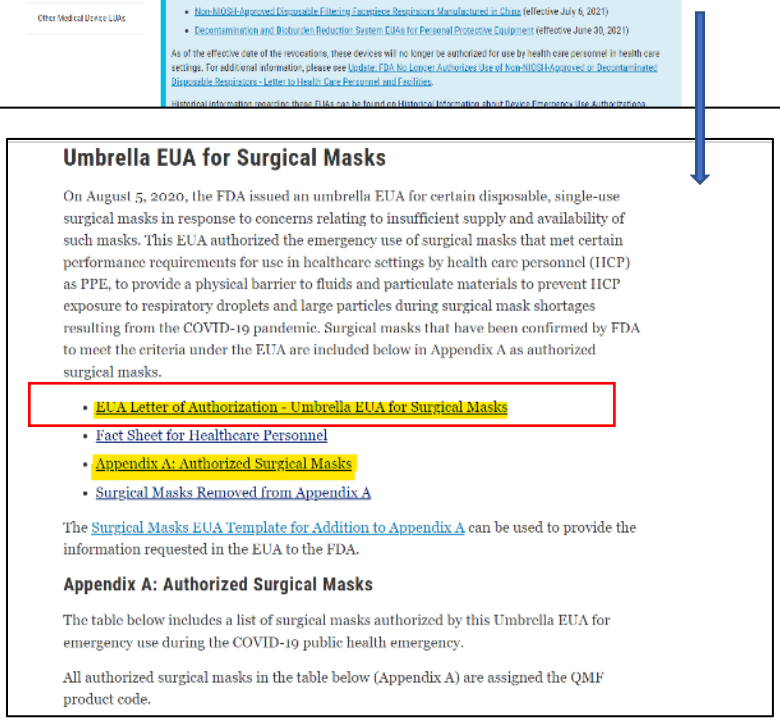
Personal Protective Equipment (PPE) refers to protective clothing, helmets, gloves, face shields, goggles, respirators or other equipment designed to protect the wearer from injury or the spread of infection or illness.

To help address concerns about availability during the COVID-19 pandemic, the FDA has issued Emergency Use Authorizations (EUAs) for certain PPE products including face shields, other barriers, and respiratory protective devices such as respirators. Additionally, the FDA has issued recommendations and policies about PPE which can be found here: Recent Final Medical Device Guidance Documents.

Templates for these EUA submissions are available to help facilitate the preparation, submission, and authorization of an EUA, including an Interactive Review Template For Non-IVD Products. Additionally, the FDA has posted a Surgical Masks EUA Template for Addition to Appendix A of the Surgical Mask Umbrella EUA.

Table of Personal Protective Equipment (PPE) EUAs

- Umbrella EUA for Surgical Masks
- N95 and Other Respirators EUAs
- Face Shields and Other Barrier EUAs



Umbrella EUA for Surgical Masks

On August 5, 2020, the FDA issued an umbrella EUA for certain disposable, single-use surgical masks in response to concerns relating to insufficient supply and availability of such masks. This EUA authorized the emergency use of surgical masks that met certain performance requirements for use in healthcare settings by health care personnel (HCP) as PPE, to provide a physical barrier to fluids and particulate materials to prevent HCP exposure to respiratory droplets and large particles during surgical mask shortages resulting from the COVID-19 pandemic. Surgical masks that have been confirmed by FDA to meet the criteria under the EUA are included below in Appendix A as authorized surgical masks.

- EUA Letter of Authorization - Umbrella EUA for Surgical Masks
- Fact Sheet for Healthcare Personnel
- Appendix A: Authorized Surgical Masks
- Surgical Masks Removed from Appendix A

The Surgical Masks EUA Template for Addition to Appendix A can be used to provide the information requested in the EUA to the FDA.

Appendix A: Authorized Surgical Masks

The table below includes a list of surgical masks authorized by this Umbrella EUA for emergency use during the COVID-19 public health emergency.

All authorized surgical masks in the table below (Appendix A) are assigned the QMF product code.

# Blanket Face Mask EUA Letter

U.S. FOOD & DRUG ADMINISTRATION

April 24, 2020

To: Manufacturers of Face Masks;
Health Care Personnel;
Hospital Purchasing Departments and Distributors; and
Any Other Stakeholders.

On April 18, 2020, in response to concerns relating to insufficient supply and availability of face masks,[1,2] the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) authorizing the use of face masks for use by members of the general public, including health care personnel (HCP)[3] in healthcare settings as personal protective equipment (PPE), to cover their noses and mouths, in accordance with Centers for Disease Control and Prevention (CDC) recommendations, to prevent the spread of the virus called severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) during the Coronavirus Disease 2019 (COVID-19) pandemic, pursuant to section 564 of the Federal, Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3).

On February 4, 2020, pursuant to Section 564(b)(1)(C) the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States

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[1] A face mask is a device, with or without a face shield, that covers the user's nose and mouth and may or may not meet fluid barrier or filtration efficiency levels. It includes cloth face coverings as a subset. It may be for single or multiple uses, and if for multiple uses it may be laundered or cleaned. There are many products marketed in the United States as "face masks" that offer a range of protection against potential health hazards. Face masks are regulated by FDA when they meet the definition of a "device" under section 201(h) of the Act. Generally, face masks fall within this definition when they are intended for a medical purpose. Face masks are regulated under 21 CFR 878.4040 as Class I 510(k)-exempt devices (non-surgical masks).

[2] Surgical masks are not covered within the scope of this authorization. Surgical masks are masks that cover the user's nose and mouth and provide a physical barrier to fluids and particulate materials and are regulated under 21 CFR 878.4040 as class II devices requiring premarket notification. Additionally, these masks meet certain fluid barrier protection standards and Class I or Class II flammability tests. More information on the distinction is provided in FDA guidance, titled "Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency" available at https://www.fda.gov/media/136449/download.

[3] HCP refers to all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials, including body substances (e.g., blood, tissue, and specific body fluids); contaminated medical supplies, devices, and equipment; contaminated environmental surfaces; or contaminated air. These HCP include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, physicians, technicians, therapists, phlebotomists, pharmacists, dentists and dental hygienists, students and trainees, contractual staff not employed by the healthcare facility, and persons not directly involved in patient care, but who could be exposed to infectious agents that can be transmitted in the healthcare setting (e.g., clerical, dietary, environmental services, laundry, security, engineering and facilities management, administrative, billing, and volunteer personnel).

# Surgical Mask EUA Letter EXCERPTS

U.S. FOOD & DRUG ADMINISTRATION

August 5, 2020

To: Manufacturers of Surgical Masks;
Health Care Personnel;
Hospital Purchasing Departments;
Authorized Distributors and Authorized Importers; and
Any Other Stakeholders

The U.S. Food and Drug Administration (FDA) is issuing this Emergency Use Authorization (EUA) in response to concerns relating to the insufficient supply and availability of disposable, single-use surgical masks[1,2] (hereafter also referred to as "surgical masks") for use in healthcare settings by health care personnel (HCP)[3] as personal protective equipment (PPE)[4] to provide a physical barrier to fluids and particulate materials to prevent HCP exposure to respiratory droplets and large particles during surgical mask shortages resulting from the Coronavirus Disease 2019 (COVID-19) pandemic, pursuant to section 564 of the Federal, Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3).

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19.[5]

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[1] A surgical mask is a mask that covers the user's nose and mouth and provides a physical barrier to fluids and particulate materials. Surgical masks are generally regulated by FDA as Class II devices under 21 CFR 878.4040 – Surgical apparel.

[2] FDA-cleared surgical face masks, non-surgical face masks, surgical masks with antimicrobial/antiviral agent, and all particulate filtering facepiece respirators are not within the scope of this authorization.

[3] For the purposes of this EUA, HCP refers to all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials, including body substances (e.g., blood, tissue, and specific body fluids); contaminated medical supplies, devices, and equipment; contaminated environmental surfaces; or contaminated air. These HCP include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, physicians, technicians, therapists, phlebotomists, pharmacists, dentists and dental hygienists, students and trainees, contractual staff not employed by the healthcare facility, and persons not directly involved in patient care, but who could be exposed to infectious agents that can be transmitted in the healthcare setting (e.g., clerical, dietary, environmental services, laundry, security, engineering and facilities management, administrative, billing, and volunteer personnel).

[4] Surgical masks may be effective in blocking splashes and large particle droplets. While surgical masks are not protective against smaller airborne particulates as described in Section II, they are considered PPE because they are intended to be used to protect HCP from infectious disease hazards. Surgical masks are different from non-surgical face masks, which are only used as source control by the general public and are not considered PPE.

[5] U.S. Department of Health and Human Services, Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3. 85 FR 7316 (February 7, 2020).

Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared on March 24, 2020, that circumstances exist justifying the authorization of emergency use of medical devices, including alternative products used as medical devices, due to shortages during the COVID-19 pandemic, subject to the terms of any authorization issued under that section.[6]

As discussed further below, I have concluded that a surgical mask meeting the criteria set forth in Section II meets the criteria for issuance of an EUA under Section 564(c) of the Act.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of surgical masks that meet the criteria set forth in Section II pursuant to the Conditions of Authorization (Section IV) of this letter (referred to in this letter as "authorized surgical masks"). Authorized surgical masks will be added to this letter of authorization in Appendix A, as described in the Scope of Authorization (Section II).

## I. Criteria for Issuance of Authorization

I have concluded that the emergency use of authorized surgical masks as described in the Scope of Authorization (Section II) of this letter for use in healthcare settings by HCP as PPE during the COVID-19 pandemic meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. SARS-CoV-2, the virus that causes COVID-19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the authorized surgical masks may be effective for use in healthcare settings by HCPs as PPE to provide a physical barrier to fluids and particulate materials to prevent HCP exposure to respiratory droplets and large particles during surgical mask shortages resulting from the COVID-19 pandemic, and that the known and potential benefits of the authorized surgical masks, when used consistent with the scope of this authorization (Section II), outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of these authorized surgical masks for use in healthcare settings by HCP to prevent HCP exposure to respiratory droplets and large particles during surgical mask shortages resulting from the COVID-19 pandemic.[7,8]

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[6] U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*, 85 FR 17335 (March 27, 2020).

[7] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

[8] There are not sufficient quantities of surgical masks to meet the needs of the U.S. healthcare system. These articles of PPE are an integral part of patient care during the COVID-19 pandemic. Providing authorization for the introduction into interstate commerce of surgical masks by manufacturers, including those that do not customarily engage in the manufacture of medical devices, helps meet the needs of the healthcare system. Providing HCP who

The labeling of the authorized surgical masks must:

- Describe the product as a disposable, single-use surgical mask. The labeling must include a list of the body contacting materials (which does not include any drugs, biologics, nanoparticles, or antimicrobial/antiviral agents);
- State that the product is not intended to replace the need for FDA-cleared surgical masks or FDA-cleared or authorized respirators;
- State that surgical masks are not intended to provide protection against pathogenic biological airborne particulates and are not recommended for use in aerosol generating procedures and any clinical conditions where there is significant risk of infection through inhalation exposure; and
- Not include statements that would misrepresent the product or create an undue risk in light of the public health emergency. For example, the labeling must not include any express or implied claims for: (1) reuse, (2) antimicrobial or antiviral protection or related uses, (3) infection prevention, infection reduction, or related uses, or (4) viral filtration efficiency.

Authorized products must be accompanied by the above required labeling, and in addition, the authorized products must be accompanied by the following information pertaining to the emergency use, which are authorized to be made available to HCPs:

- Fact Sheet for Healthcare Personnel: Emergency Use of Authorized Disposable, Single-Use Surgical Masks During the COVID-19 Pandemic

The manufacturer's labeling (which must meet the labeling requirements specified above ) and the fact sheet, are referred to as "authorized labeling."

FDA may remove an authorized surgical mask from Appendix A of this EUA if FDA has reason to believe that the product no longer meets the Scope of Authorization (Section II) or any of the Conditions of Authorization (Section IV). FDA will provide the manufacturer 24 hours advance notice of such removal and may work with the manufacturer to resolve the issue(s) that led to removal of the device(s) from Appendix A. Products that are removed from Appendix A will appear on a list maintained on FDA's website.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of authorized surgical masks as described within this section (the Scope of Authorization, Section II), outweigh the known and potential risks of such products.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that authorized surgical masks may be effective as described within this section (the Scope of Authorization, Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that authorized surgical masks (as described in the Scope of Authorization, Section II), meet the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of authorized surgical masks must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), surgical masks that are determined to meet the criteria set forth in this section (Section II) are authorized under the terms and conditions of this EUA.

**III. Waiver of Certain FDA Requirements**

Waiving Good Manufacturing means less oversight and less QA/QC...so less safe and more RISK for YOU!

I am waiving applicable current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the authorized surgical masks that are used in accordance with this EUA.

**IV. Conditions of Authorization**

Pursuant to Section 564(e) of the Act, I am establishing the following conditions to this authorization:

**Manufacturers of Authorized Products**

A. Manufacturers will make authorized products available with the authorized labeling (including the labeling requirements described in Section II). Manufacturers must make available all labeling in English, to each end user facility (e.g., each hospital) that receives the authorized products, and may include the authorized labeling with each individual authorized product.

B. Manufacturers must comply with 21 CFR Part 803, and must have a process in place for reporting adverse events of which they become aware to FDA consistent with 21 CFR Part 803. See FDA's webpage "Medical Device Reporting (MDR): How to Report Medical Device Problems"[12] for additional information concerning reporting requirements under 21 CFR Part 803 and procedures.

C. Manufacturers will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

[12] FDA guidance, titled "Medical Device Reporting (MDR): How to Report Medical Device Problems" is available at https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

This means the manufacturer cannot advertise that masks prevent the spread...

**Conditions Related to Advertising and Promotion**

L. All descriptive printed matter, including advertising and promotional materials, relating to the use of the authorized surgical mask shall be consistent with the labeling requirements listed in Section II and this section (Conditions of Authorization) of this EUA, and the applicable requirements set forth in the Act and FDA regulations.

M. No descriptive printed matter, including advertising or promotional materials, relating to the use of the authorized surgical mask may represent or suggest that such product is safe or effective for the prevention or treatment of COVID-19.

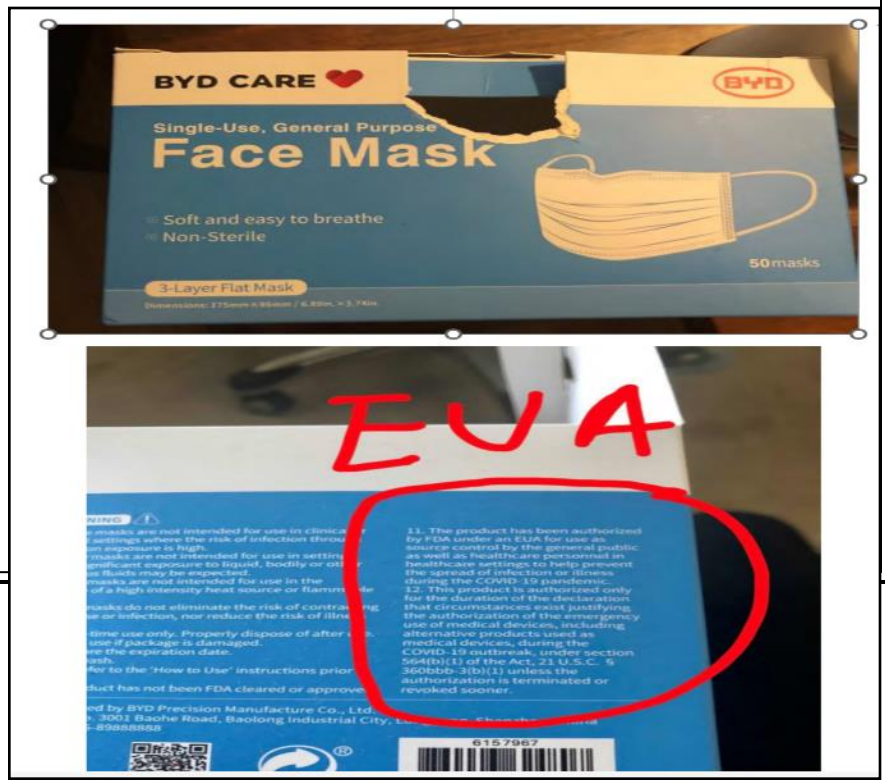
N. All descriptive printed matter, including advertising and promotional materials, relating to the use of the product shall clearly and conspicuously state that:

This means masks ARE NOT LICENSED to PREVENT COVID-19

- The product has not been FDA cleared or approved.
- The product has been authorized by FDA under an EUA for use in healthcare settings by HCP as PPE to provide a physical barrier to fluids and particulate materials to prevent HCP exposure to respiratory droplets and large particles during surgical mask shortages resulting from the COVID-19 pandemic.
- This product is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices, including alternative products used as medical devices, during the COVID-19 outbreak, under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1) unless the authorization is terminated or revoked sooner.

**V. Duration of Authorization**

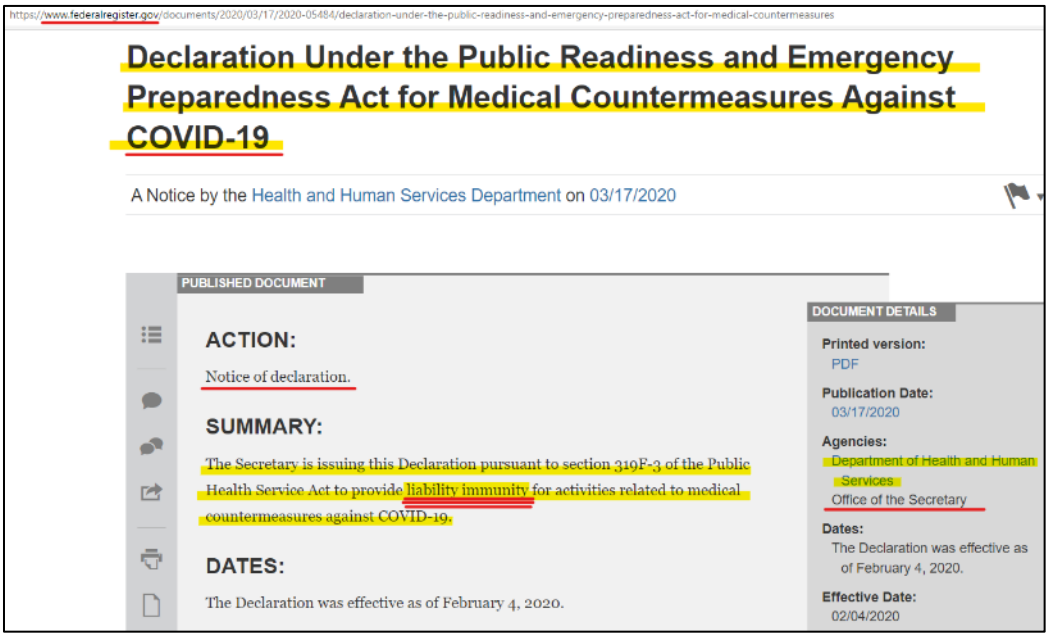
This EUA will be effective until the declaration that circumstances exist justifying this authorization is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.



4. Locate the EUA Publication in the Federal Register because the Secretary of HHS (Thru the FDA) must publish updates to products granted Emergency Use Authorization and revocations within 21 U.S.C. § 360bbb-3(h). Also, in order to grant an EUA or liability protections, the Secretary HHS must declare a public health emergency via delegated statutory authority granted in 42 U.S.C. § 247d-6d.

A. Emergency Public Health Declaration. The Secretary of HHS initiated the Public Health Emergency Declaration in February 2020 and posted the Declaration into the Federal Register on 17 March 2020.

- Statutory Authority to issue the Public Emergency Declaration Comes from 42 U.S.C. § 247d-6d


https://www.federalregister.gov/documents/2020/03/17/2020-05484/declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical-countermeasures

**Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19**

A Notice by the Health and Human Services Department on 03/17/2020

PUBLISHED DOCUMENT

**ACTION:**

Notice of declaration.

**SUMMARY:**

The Secretary is issuing this Declaration pursuant to section 319F-3 of the Public Health Service Act to provide liability immunity for activities related to medical countermeasures against COVID-19.

**DATES:**

The Declaration was effective as of February 4, 2020.

DOCUMENT DETAILS

**Printed version:**
PDF

**Publication Date:**
03/17/2020

**Agencies:**
Department of Health and Human Services
Office of the Secretary

**Dates:**
The Declaration was effective as of February 4, 2020.

**Effective Date:**
02/04/2020

(This is the formal Public Health Emergency for COVID19; the declaration activates liability immunity for covered persons, covered countermeasures against covered conditions)

- 42 USC CHAPTER 6A, SUBCHAPTER II, Part F, subpart 1: biological products (house.gov) Liability Protection Crosswalk

**(b) Declaration by Secretary**

**(1) Authority to issue declaration**

Subject to paragraph (2), if the Secretary makes a determination that a disease or other health condition or other threat to health constitutes a public health emergency, or that there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency, the Secretary may make a declaration, through publication in the Federal Register, recommending, under conditions as the Secretary may specify, the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures, and stating that subsection (a) is in effect with respect to the activities so recommended.

(Authority to Declare Public Health Emergency)

**§247d–6d. Targeted liability protections for pandemic and epidemic products and security countermeasures**

**(a) Liability protections**

**(1) In general**

Subject to the other provisions of this section, a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if a declaration under subsection (b) has been issued with respect to such countermeasure.

**(2) Scope of claims for loss**

**(A) Loss**

For purposes of this section, the term "loss" means any type of loss, including-

(i) death;
(ii) physical, mental, or emotional injury, illness, disability, or condition;
(iii) fear of physical, mental, or emotional injury, illness, disability, or condition, including any need for medical monitoring; and
(iv) loss of or damage to property, including business interruption loss.

Each of clauses (i) through (iv) applies without regard to the date of the occurrence, presentation, or discovery of the loss described in the clause.

**(B) Scope**

The immunity under paragraph (1) applies to any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure, including a causal relationship with the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure.

(Covered Conditions)

**(i) Definitions**

In this section:

**(1) Covered countermeasure**

The term "covered countermeasure" means-

(A) a qualified pandemic or epidemic product (as defined in paragraph (7));
(B) a security countermeasure (as defined in section 247d–6b(c)(1)(B) of this title);
(C) a drug (as such term is defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)), biological product (as such term is defined by section 262(i) of this title), or device (as such term is defined by section 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(h)) that is authorized for emergency use in accordance with section 564, 564A, or 564B of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360bbb–3, 360bbb–3a, 360bbb–3b]; or
(D) a respiratory protective device that is approved by the National Institute for Occupational Safety and Health under part 84 of title 42, Code of Federal Regulations (or any successor regulations), and that the Secretary determines to be a priority for use during a public health emergency declared under section 247d of this title.

(Covered Countermeasures…see Device highlighted as defined or under an EUA..so YES a device-Test Kit and Mask are COVERED COUNTERMEAUSRES and HAVE LIABILITY PROTECTIONS…YOU HAVE LITTLE LEGAL RECOURSE against any DAMAGE)

- Covered Countermeasures: ALL unapproved EUA products fall into this category. Once granted an EUA, they receive liability immunity as a covered countermeasure.
    - **YOU ACCEPT ALL RISK**
- Understanding this legal fact is why YOU have the INHERENT right to REFUSE EUA products and why you MUST be INFORMED (informed consent)

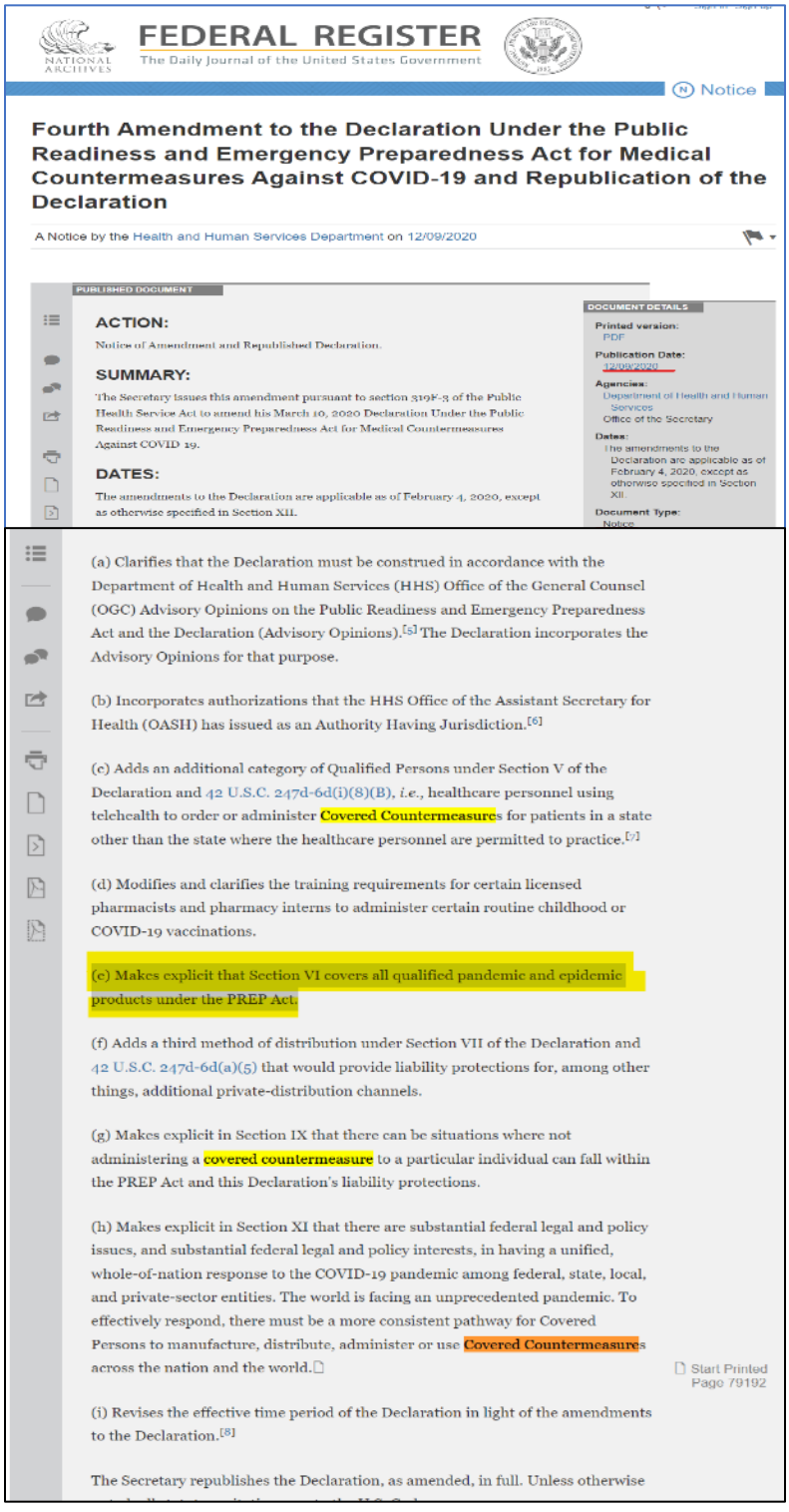
**(2) Covered person**

The term "covered person", when used with respect to the administration or use of a covered countermeasure, means-

(A) the United States; or
(B) a person or entity that is-
(i) a manufacturer of such countermeasure;
(ii) a distributor of such countermeasure;
(iii) a program planner of such countermeasure;
(iv) a qualified person who prescribed, administered, or dispensed such countermeasure; or
(v) an official, agent, or employee of a person or entity described in clause (i), (ii), (iii), or (iv).

(Covered Persons)

- An official, Agent, or Employee means that **YOUR COMMANDERs, OUR LEADERSHIP, OUR SJAs**, and **HEALTHCARE** Members are covered persons and do NOT have an incentive to check into matters. You must let them know they are covered persons and educate them on what this means.



FEDERAL REGISTER
The Daily Journal of the United States Government

Notice

# Fourth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration

A Notice by the Health and Human Services Department on 12/09/2020

PUBLISHED DOCUMENT

**ACTION:**

Notice of Amendment and Republished Declaration.

**SUMMARY:**

The Secretary issues this amendment pursuant to section 319F-3 of the Public Health Service Act to amend his March 10, 2020 Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID 19.

**DATES:**

The amendments to the Declaration are applicable as of February 4, 2020, except as otherwise specified in Section XII.

DOCUMENT DETAILS

Printed version:
PDF

Publication Date:
12/09/2020

Agencies:
Department of Health and Human Services
Office of the Secretary

Dates:
The amendments to the Declaration are applicable as of February 4, 2020, except as otherwise specified in Section XII.

Document Type:
Notice

(a) Clarifies that the Declaration must be construed in accordance with the Department of Health and Human Services (HHS) Office of the General Counsel (OGC) Advisory Opinions on the Public Readiness and Emergency Preparedness Act and the Declaration (Advisory Opinions).[5] The Declaration incorporates the Advisory Opinions for that purpose.

(b) Incorporates authorizations that the HHS Office of the Assistant Secretary for Health (OASH) has issued as an Authority Having Jurisdiction.[6]

(c) Adds an additional category of Qualified Persons under Section V of the Declaration and 42 U.S.C. 247d-6d(i)(8)(B), *i.e.*, healthcare personnel using telehealth to order or administer Covered Countermeasures for patients in a state other than the state where the healthcare personnel are permitted to practice.[7]

(d) Modifies and clarifies the training requirements for certain licensed pharmacists and pharmacy interns to administer certain routine childhood or COVID-19 vaccinations.

(e) Makes explicit that Section VI covers all qualified pandemic and epidemic products under the PREP Act.

(f) Adds a third method of distribution under Section VII of the Declaration and 42 U.S.C. 247d-6d(a)(5) that would provide liability protections for, among other things, additional private-distribution channels.

(g) Makes explicit in Section IX that there can be situations where not administering a covered countermeasure to a particular individual can fall within the PREP Act and this Declaration's liability protections.

(h) Makes explicit in Section XI that there are substantial federal legal and policy issues, and substantial federal legal and policy interests, in having a unified, whole-of-nation response to the COVID-19 pandemic among federal, state, local, and private-sector entities. The world is facing an unprecedented pandemic. To effectively respond, there must be a more consistent pathway for Covered Persons to manufacture, distribute, administer or use Covered Countermeasures across the nation and the world.

Start Printed Page 79192

(i) Revises the effective time period of the Declaration in light of the amendments to the Declaration.[8]

The Secretary republishes the Declaration, as amended, in full. Unless otherwise

([4th Amendment to Emergency Declaration as an example…it is all about providing everyone BUT you with Liability Immunity, 20 Dec 2020])

## 5. Depict and Communicate, and show our Individual Compensation Realities for Taking a Covered Countermeasure

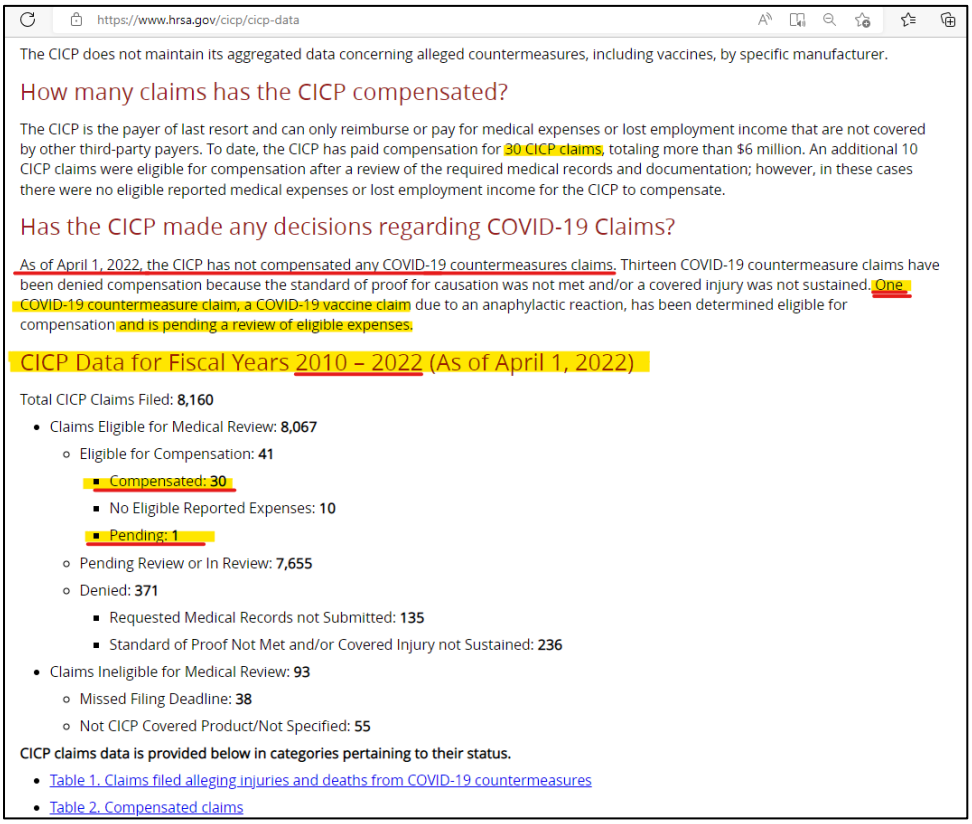
You ideally should be informed of the CICP by any medical provider for taking an EUA product because again, you accept all of the risk once you take these untested, unlicensed products. The long-term studies are not there to support the potential injuries you could suffer as a result of taking any of these EUA products.

**This leads to the natural legal/curious question: What is my legal recompense if I suffer an injury from using an EUA product (mask/test Kit/shots/drugs)?**

Americans have the right file a lawsuit if they are directly injured by the vaccine, test kit, masks, and drugs. However, given the covered persons status (liability immunity) afforded to EUA products under 42 USC § 427d-6d, lawsuits must be filed through the Countermeasures Injury Compensation Program (CICP)

To date, there are approximately 8,000 claims in using the CICP and so far, the US Government has paid $0 in damage awards.

To determine the likelihood of getting compensated, reference the U.S. government's Health Resources and Services Administration website, [Countermeasures Injury Compensation Program (CICP) Data | Official web site of the U.S. Health Resources & Services Administration (hrsa.gov)](https://www.hrsa.gov/cicp/cicp-data):



https://www.hrsa.gov/cicp/cicp-data

The CICP does not maintain its aggregated data concerning alleged countermeasures, including vaccines, by specific manufacturer.

### How many claims has the CICP compensated?

The CICP is the payer of last resort and can only reimburse or pay for medical expenses or lost employment income that are not covered by other third-party payers. To date, the CICP has paid compensation for 30 CICP claims, totaling more than $6 million. An additional 10 CICP claims were eligible for compensation after a review of the required medical records and documentation; however, in these cases there were no eligible reported medical expenses or lost employment income for the CICP to compensate.

### Has the CICP made any decisions regarding COVID-19 Claims?

As of April 1, 2022, the CICP has not compensated any COVID-19 countermeasures claims. Thirteen COVID-19 countermeasure claims have been denied compensation because the standard of proof for causation was not met and/or a covered injury was not sustained. One COVID-19 countermeasure claim, a COVID-19 vaccine claim due to an anaphylactic reaction, has been determined eligible for compensation and is pending a review of eligible expenses.

### CICP Data for Fiscal Years 2010 – 2022 (As of April 1, 2022)

Total CICP Claims Filed: **8,160**

- Claims Eligible for Medical Review: **8,067**
  - Eligible for Compensation: **41**
    - Compensated: **30**
    - No Eligible Reported Expenses: **10**
    - Pending: **1**
  - Pending Review or In Review: **7,655**
  - Denied: **371**
    - Requested Medical Records not Submitted: **135**
    - Standard of Proof Not Met and/or Covered Injury not Sustained: **236**
- Claims Ineligible for Medical Review: **93**
  - Missed Filing Deadline: **38**
  - Not CICP Covered Product/Not Specified: **55**

**CICP claims data is provided below in categories pertaining to their status.**

- Table 1. Claims filed alleging injuries and deaths from COVID-19 countermeasures
- Table 2. Compensated claims

Over a period of almost 12 years, 8,160 Countermeasures Injury Compensation Program (CICP) claims were filed (most of these during the COVID19 pandemic). Of these TOTAL claims, only 30 CICP claims have been compensated, resulting in $6 million paid out over 12 years.

Despite over 1.25 million individuals that reported adverse events due to COVID-19 vaccines, no individual to date received a single dollar in damage awards. Only one COVID-19 CICP claim is pending.

It is worth noting there is a separate program for FDA-approved vaccine injuries-- the Vaccine Injury Compensation Program (VICP), which has an annual budget of several billion dollars for compensation payouts.

The following chart shows the difference between filing a claim for CICP and VICP Comparison of Countermeasures Injury Compensation Program (CICP) to the National Vaccine Injury Compensation Program (VICP) | Official web site of the U.S. Health Resources & Services Administration (hrsa.gov):

## Comparison of Countermeasures Injury Compensation Program (CICP) to the National Vaccine Injury Compensation Program (VICP)

| Program Categories | CICP | VICP |
|---|---|---|
| Program Authorization | Public Readiness and Emergency Preparedness Act (PREP Act) (42 U.S.C. §§ 247d-6d, 247d-6e) | National Childhood Vaccine Injury Act of 1986, as amended (42 U.S.C. § 300aa-10, et seq.) |
| Payment of Legal Fees and Costs | Attorneys' fees and costs are not paid by the program. | Attorneys' fees and costs may be available if certain requirements are met (petition filed in good faith and on a reasonable basis) |
| Persons who can file Requests/ Petitions | Types of Eligible Requesters | Who Can File a Petition? |
| Process for Filing a Request/Petition | File the Request Form and documentation with the Secretary of HHS. | File petition and documentation with the U.S. Court of Federal Claims and the Secretary of HHS. |
| Process for Resolving Requests/ Petitions | Administrative Process | Judicial Process |
| Covered Injury Determinations | HHS makes decision. Criteria to Demonstrate that a Covered Injury Occurred | Special Masters (or judges) of U.S. of Court of Federal Claims make decision. Criteria to be Found Eligible to Receive Compensation |
| Appeal Rights | One step administrative reconsideration possible. No judicial appeal permitted. | Judicial appeal by either party to higher courts possible. |
| Program Funding | Appropriated Funds | Vaccine Injury Compensation Trust Fund funded through excise taxes on covered vaccines. Congress annually appropriates funding from the Trust Fund to the Health Resources and Services Administration (HRSA), Department of Justice, and U.S. Court of Federal Claims to pay their expenses to administer the VICP and to HRSA to compensate VICP claims. |

All COVID-19 products have liability immunity protection under 42 USC § 247d-6d. As a result, all COVID-19 products fall under the CICP (i.e. vaccines, tests, masks, etc.). To initiate a claim, a vaccine injured person is required to pay for attorney fees and costs since those fees and costs. The CICP request/petition is filed with the HHS Secretary, the same individual who authorized emergency use of the products. The HHS Secretary also makes the determination regarding legitimacy of a claim and is also the appeal authority. There is also no judicial process.

VICP exists because under the National Childhood Vaccine Injury Act of 1986, which protects vaccine manufacturers from being sued for damages.

Injuries from other emergency use products are also adjudicated through CICP [Countermeasures Injury Compensation Program (CICP) Data | Official web site of the U.S. Health Resources & Services Administration (hrsa.gov)](). The following chart shows multiple requests/petitions for COVID-19 tests:

| | | |
|---|---|---|
| COVID-19 Medications | Death | 11 |
| COVID-19 Medications / Intubation | Death | 1 |
| COVID-19 Medications / Remdesivir | Death | 1 |
| COVID-19 Test | Death | 2 |
| COVID-19 Test | Perforated Ethmoidal Artery | 1 |
| COVID-19 Test | Punctured Brain / CSF | 1 |
| COVID-19 Test / Heparin / Supplemental Oxygen / Ultrasound (Duplex) | Brain Injury / Quadriplegia | 1 |
| COVID-19 Test / Oxygen | Death | 1 |
| COVID-19 Vaccine | Abdominal and Chest Pain / High Blood Pressure | 1 |
| COVID-19 Vaccine | Abdominal Pain | 3 |
| COVID-19 Vaccine | Abdominal Pain / Body Aches / Chills / Diarrhea / Headaches / Nausea / Vomiting | 1 |

**TEST KITS/MASKS:** Individuals have filed requests/petitions for COVID-19 tests and masks. This fact also shows that masks/test kits are INDEED EUA PRODUCTS and are UNAPPROVED (UNLICENSED), are COVERED COUNTERMEASURES, and ALL have liability protections under 42 USC § 247d-6d.

**FINAL KEY POINT:** If the products were in fact FDA **approved and individuals suffered harm, then an individual would be able to sue the manufacturers**. But because of the liability immunity protection afforded under 42 USC § 247d-6d and by being legally defined and authorized as an Unapproved product as defined in 21 USC § 360bbb-3 subsection (e):

**YOU ALWAYS HAVE THE LEGAL RIGHT TO REFUSE THESE PRODUCTS because YOU ACCEPT ALL THE RISK!**

1. So according to 21 USC § 360bbb-3 and 21 U.S.C. § 321 are masks legally defined as a medical product? Yes, they are both legally considered a medical device?

2. Are Masks and Test Kits “approved” products (legally licensed) to prevent, treat, cure, and diagnose SARS COV 2 or COVID19?

There are NO licensed Test Kits and Masks available in the US Market and ALL test kits and masks are EUA medical devices that are also considered “covered countermeasures” receiving full liability protections under 42 USC § 247d-6d. All test Kits and masks are unlicensed and unapproved products 21 USC § 360bbb-3 (e)(1)(A). If the FDA approved (licensed a mask or test kit) then all other EUA products in the respective category lose their EUA justification because the US market would then have a licensed product to diagnose or prevent the spread of COVID19.

**(e) Conditions of authorization**

**(1) Unapproved product**

**(A) Required conditions**

With respect to the emergency use of an unapproved product, the Secretary, to the extent practicable given the applicable circumstances described in subsection (b)(1), shall, for a person who carries out any activity for which the authorization is issued, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including the following:

(i) Appropriate conditions designed to ensure that health care professionals administering the product are informed—

(I) that the Secretary has authorized the emergency use of the product;

(II) of the significant known and potential benefits and risks of the emergency use of the product, and of the extent to which such benefits and risks are unknown; and

(III) of the alternatives to the product that are available, and of their benefits and risks.

(ii) Appropriate conditions designed to ensure that individuals to whom the product is administered are informed—

(I) that the Secretary has authorized the emergency use of the product;

(II) of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and

(III) of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.

(iii) Appropriate conditions for the monitoring and reporting of adverse events associated with the emergency use of the product.

(iv) For manufacturers of the product, appropriate conditions concerning recordkeeping and reporting, including records access by the Secretary, with respect to the emergency use of the product.

**(B) Authority for additional conditions**

With respect to the emergency use of an unapproved product, the Secretary may, for a person who carries out any activity for which the authorization is issued, establish such conditions on an authorization under this section

(B) Additive to Required Conditions, HHS Can Add conditions, they cannot take away from **required conditions**

9/34

**(2) Termination of declaration**

**(A) In general**

A declaration under this subsection shall terminate upon the earlier of—

(i) a determination by the Secretary, in consultation as appropriate with the Secretary of Homeland Security or the Secretary of Defense, that the circumstances described in paragraph (1) have ceased to exist; or

(ii) a change in the approval status of the product such that the circumstances described in subsection (a)(2) have ceased to exist.

3. How do I show that test kits and Masks are unapproved medical products (unlicensed) with a granted Emergency Use Authorization?

A. First step, in accordance with 42 USC § 247d-6d. The Secretary of HHS declares a public health emergency. The SEC HHS declared the SARS-COV-2/COVID19 Public Health Emergency in February 2020. The HHS posted the formal declaration on the Federal Register on 17 March 2020. Subsequent to this declaration, the Secretary of HHS and the FDA (subordinate of HHS) review and recommend/authorize products for emergency use.

B. **Do the legal definition Crosswalk and Show and Tell**

(1) In accordance with 21 USC § 360bbb-3 (a) (2)(A) are any test kits or masks approved (legally licensed) to treat, cure, prevent, or diagnose COVID19.

NO mask or test kit are licensed or approved and by legal definitions fall under the unapproved product definition and can be considered for authorization under emergency use as a covered countermeasure by the FDA to prevent, treat, diagnose, or cure COVID19.

**§360bbb–3. Authorization for medical products for use in emergencies**

**(a) In general**

**(1) Emergency uses**

Notwithstanding any provision of this chapter and section 351 of the Public Health Service Act [42 U.S.C. 262], and subject to the provisions of t
a declaration under subsection (b), of a drug, device, or biological product intended for use in an actual or potential emergency (referred to in this s

**(2) Approval status of product**

An authorization under paragraph (1) may authorize an emergency use of a product that-

(A) is not approved, licensed, or cleared for commercial distribution under section 355, 360(k), 360b, or 360e of this title or section 351 of the
in this section as an "unapproved product"); or

(B) is approved, conditionally approved under section 360ccc of this title, licensed, or cleared under such a provision, but which use is not unc
of the product (referred to in this section as an "unapproved use of an approved product").

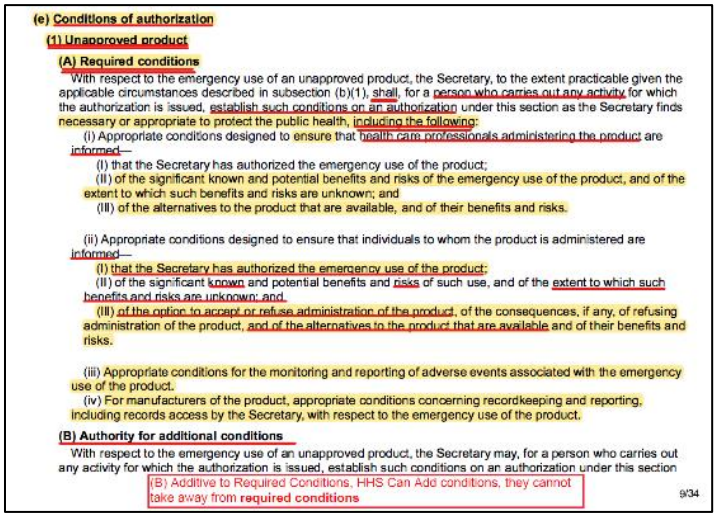
**(3) Relation to other uses**

An emergency use authorized under paragraph (1) for a product is in addition to any other use that is authorized for the product under a section

**(4) Definitions**

For purposes of this section:

(A) The term "biological product" has the meaning given such term in section 351 of the Public Health Service Act [42 U.S.C. 262].
(B) The term "emergency use" has the meaning indicated for such term in paragraph (1).
(C) The term "product" means a drug, device, or biological product.
(D) The term "unapproved product" has the meaning indicated for such term in paragraph (2)(A).
(E) The term "unapproved use of an approved product" has the meaning indicated for such term in paragraph (2)(B).



**(e) Conditions of authorization**

**(1) Unapproved product**

**(A) Required conditions**

With respect to the emergency use of an unapproved product, the Secretary, to the extent practicable given the applicable circumstances described in subsection (b)(1), shall, for a person who carries out any activity for which the authorization is issued, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including the following:

(i) Appropriate conditions designed to ensure that health care professionals administering the product are informed—

(I) that the Secretary has authorized the emergency use of the product;

(II) of the significant known and potential benefits and risks of the emergency use of the product, and of the extent to which such benefits and risks are unknown; and

(III) of the alternatives to the product that are available, and of their benefits and risks.

(ii) Appropriate conditions designed to ensure that individuals to whom the product is administered are informed—

(I) that the Secretary has authorized the emergency use of the product;

(II) of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and

(III) of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.

(iii) Appropriate conditions for the monitoring and reporting of adverse events associated with the emergency use of the product.

(iv) For manufacturers of the product, appropriate conditions concerning recordkeeping and reporting, including records access by the Secretary, with respect to the emergency use of the product.

**(B) Authority for additional conditions**

With respect to the emergency use of an unapproved product, the Secretary may, for a person who carries out any activity for which the authorization is issued, establish such conditions on an authorization under this section

(B) Additive to Required Conditions. HHS Can Add conditions, they cannot take away from **required conditions**

9/34

(2) Are test kits a medical device as defined in 21 USC § 360bbb-3 and 21 U.S.C. § 321 and are they unlicensed for COVID19? YES, test kits and masks are medical devices, and are unapproved, unlicensed, and must state this unequivocally and conspicuously.

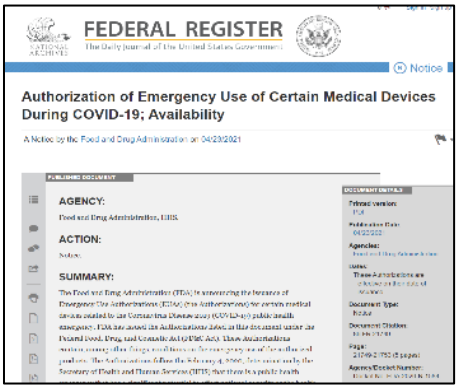
C. Further Proof of EUA Status: **21 USC § 360bbb-3 (h)** Requires the Dept. of Health and Human Services (Thru the FDA) to publicly update and provide notices on all products authorized for emergency use as well as revocations. Also supporting this EUA Letters on the FDA Website, Product Boxes, Inserts, and Each EUA Letter states the respective Masks or Test Kits are unapproved and requires ALL manufacturers to "conspicuously" label each package and package insert to reflect these products are not FDA approved or FDA Cleared (means it is unapproved and unlicensed).

**(h) Publication; confidential information**

**(1) Publication**

The Secretary shall promptly publish in the Federal Register a notice of each authorization, and each termination or revocation of an authorization under this section, and an explanation of the reasons therefor (which may include a summary of data or information that has been submitted to the Secretary in an application under section 355(i) [1] 360b(j), or 360j(g) of this title, even if such summary may indirectly reveal the existence of such application). The Secretary shall make any revisions to an authorization under this section available on the Internet Web site of the Food and Drug Administration.

*Figure 1: Federal Register EUA NOTICE 23 APR21*



FEDERAL REGISTER

Notice

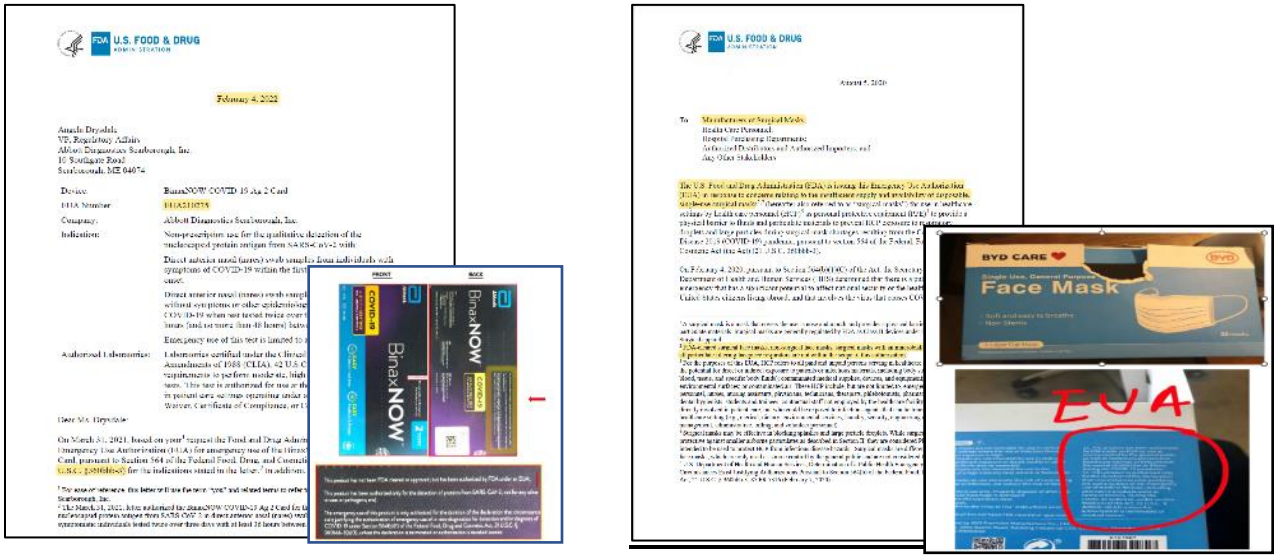
**Authorization of Emergency Use of Certain Medical Devices During COVID-19; Availability**

AGENCY:

ACTION:

SUMMARY:

*Figure 2 BinaxNow EUA Letter (9 Nov 2021) and Surgical Mask EUA Letter (w/pictures stating these products are EUA*




C. Are Masks/Test Kits considered “Covered Countermeasures” and do they receive liability protections in 42 USC § 247d-6d I read so much about in this document? Yes, test kits and masks are medical devices, unlicensed, and all are under an EUA granted by the FDA.

Covered Countermeasures grant liability protections and place any damage claims against a covered countermeasure through the Countermeasure Injury Compensation Program (CICP). In order to even be placed into the CICP, the product must be an unapproved (unlicensed) product under EUA for a declared public health emergency.

**(i) Definitions**

In this section:

**(1) Covered countermeasure**

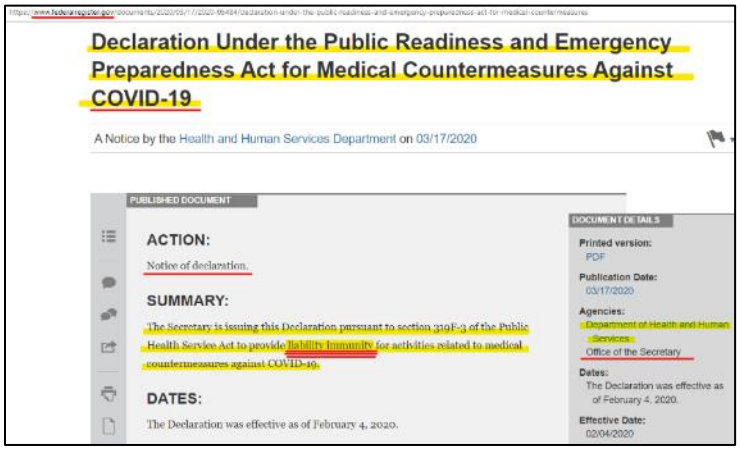
The term "covered countermeasure" means-

(A) a qualified pandemic or epidemic product (as defined in paragraph (7));

(B) a security countermeasure (as defined in section 247d–6b(c)(1)(B) of this title);

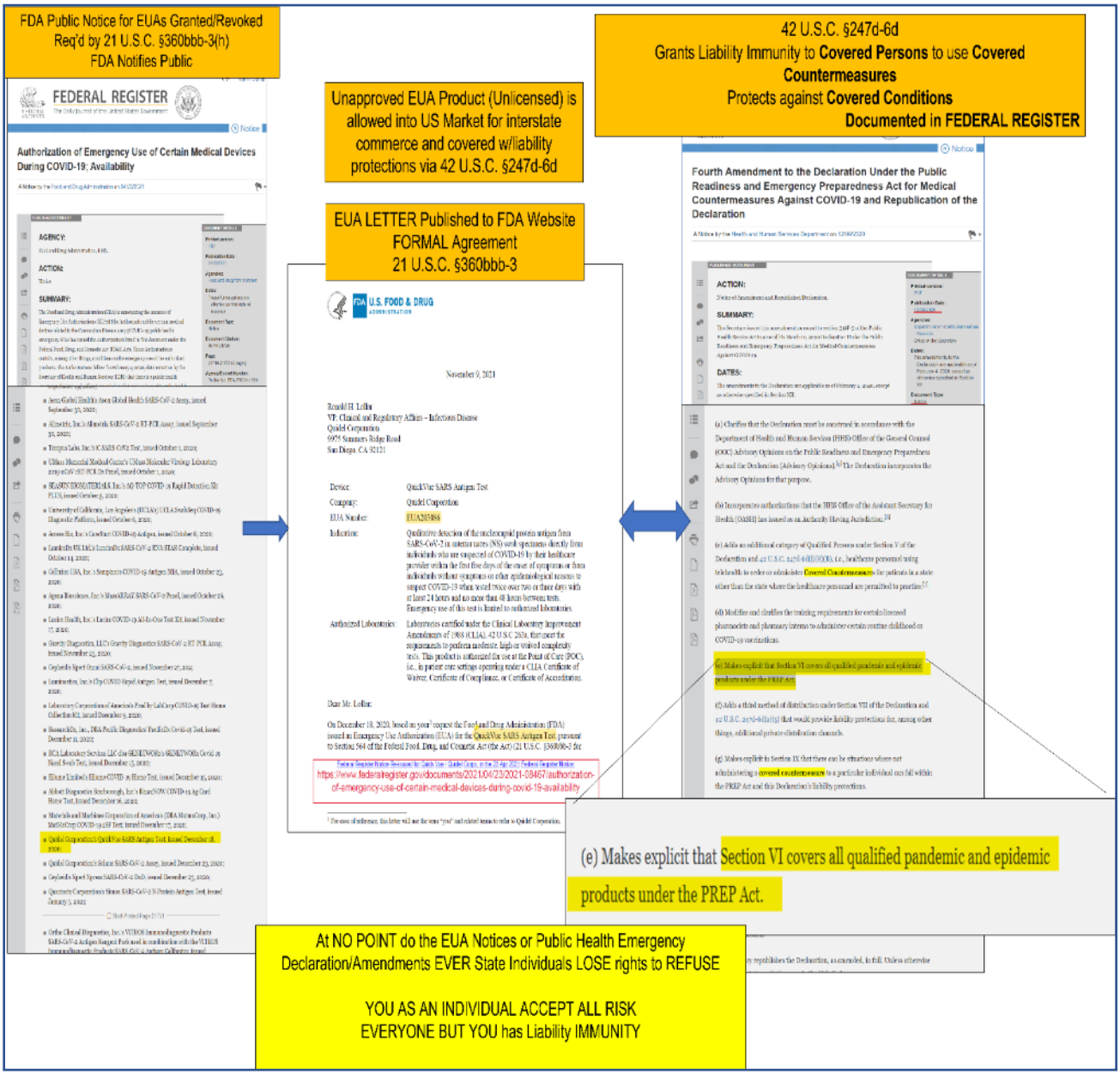
(C) a drug (as such term is defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)), biological product (as such term is defined by section 262(i) of this title), or device (as such term is defined by section 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(h)) that is authorized for emergency use in accordance with section 564, 564A, or 564B of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360bbb–3, 360bbb–3a, 360bbb–3b]; or

(D) a respiratory protective device that is approved by the National Institute for Occupational Safety and Health under part 84 of title 42, Code of Federal Regulations (or any successor regulations), and that the Secretary determines to be a priority for use during a public health emergency declared under section 247d of this title.




The COVID19 Public Health Emergency declaration clearly articulates liability immunity for involved parties (i.e. the government and product manufacturers). Also at no point do EUA notices or Amendments ever state an individual (or servicemember) ever lose their right to refuse these products. **The term “liability immunity” appeared 31 times in the original declaration**

## 6. Understand the Connections




- Yes, Masks and Test Kits are **<u>UNEQUIVOCALLY UNAPPROVED</u>** (Unlicensed) Products, and ALL Have **<u>REQUIRED</u>** conditions granted through 21 U.S.C. § 360bbb-3(e)(1)(A).
- ALL EUA Products for COVID19 in the US Market (yes even masks and test kits) are EUA, unapproved, and ALL rights to refuse fully apply. Mandates are unlawful coercion and violate the same EUA statutory laws found in 21 U.S.C. § 360bbb-3(e)(1)(A)
- 42 U.S.C. § 247d-6d grants COVID19 EUA Products (shots, masks, test kits) liability protections. THEY CAN ONLY RECEIVE THESE PROTECTIONS THRU A DECLARED EMERGENCY and ONLY If they are UNLICENSED/UNAPPROVED! Also granted via 42 U.S.C. § 247d-6d by the Secretary HHS

REFERENCES

## Federal Laws

42 USC 247d-6d: Targeted liability protections for pandemic and epidemic products and security countermeasures (house.gov) This is the key law that provides manufacturers, governments, distributors, healthcare workers, and other identified covered persons the liability immunity protections...this law alone provides the moral hazard and incentives to keep products under EUA and to direct people to take EUA shots because they are "interchangeable." This portion of Title 42 also provides the Secretary of Health and Human Services the statutory authority to declare Public Health Emergencies.

42 USC 262: Regulation of biological products (house.gov) - Legal requirements for Biological Product [shot] licensing and interchangeability. There is no LEGAL definition of a “BLA Compliant” Biological product.

21 USC 360bbb-3: Authorization for medical products for use in emergencies (house.gov) – The right to accept or refuse EUA products.

21 USC 321: Definitions; generally (house.gov) – Definitions.

eCFR :: 21 CFR Part 50 -- Protection of Human Subjects - [21 Code of Federal Regulations - Legal requirements for government agencies to comply with **informed consent and human subjects**]

10 USC 1107a: Emergency use products (house.gov) – Discusses EUA products as they relate to the armed forces.

10 USC 1107: Notice of use of an investigational new drug or a drug unapproved for its applied use (house.gov) - Notification requirements in the event the President waives the requirement for service members to be notified of the right to refuse an EUA product.

Nuremberg Code - history - Office of NIH History and Stetten Museum

## Federal Register Notices

Federal Register :: Authorizations of Emergency Use of Certain Biological Products During the COVID-19 Pandemic; Availability – The Federal Register is the federal repository of documents, published daily, which includes proposed federal rules, proposed rules, notices, and executive orders and other presidential documents.

Public Readiness and Emergency Preparedness Act (hhs.gov) - Contains links to ALL COVID 19 Emergency Declaration Amendments.

Federal Register :: Document Search Results for 'Covid 19 Emergency Use Authorization'- Contains the filtered search of Public Health Emergency Notices (Declarations and Amendments) and the Emergency Use Authorization Notices. You can filter and sort by chronological order.

IIS COVID-19 Vaccine Related Code | CDC (COVID19 EUA/BLA Shots in Market, Rollup of Legal Status/availability

## FDA EUA Letters (Includes EUA letters for all COVID-19 products):

- Emergency Use Authorization | FDA – Master Page - FDA Webpage for Covered Countermeasures/EUA Products-Letters by Product Type

- Emergency Use Authorization | FDA - Biologic Products, such as vaccines
- Emergency Use Authorization | FDA – Drugs, such as remdesivir and ivermectin
- Emergency Use Authorization | FDA - Medical Devices, such as tests and masks
- In Vitro Diagnostics EUAs - Antigen Diagnostic Tests for SARS-CoV-2 | FDA - Test kits

- Spikevax and Moderna COVID-19 Vaccine | FDA
- Comirnaty and Pfizer-BioNTech COVID-19 Vaccine | FDA

Comparison of Countermeasures Injury Compensation Program (CICP) to the National Vaccine Injury Compensation Program (VICP) | Official web site of the U.S. Health Resources & Services Administration (hrsa.gov) - All EUA products authorized for COVID-19 are considered "covered countermeasures." This means they have liability protection and the only recourse is through the Countermeasure Injury Compensation Program (CICP)....all products under EUA are covered under the CICP since they are unapproved products under EUA.

FDA Purplebook- This links to the Spikevax and Comirnaty page, which indicates there are no biosimilar/interchangeable products available.