

COVID-19 Vaccine Update

October 2021



MEMBERSHIP
MOVES
MEDICINE™



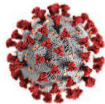
Sandra Adamson Fryhofer MD

Chair-Elect, AMA Board of Trustees

AMA Liaison to CDC's Advisory Committee on Immunization Practices (ACIP)

Member, ACIP's COVID -19 Vaccine Work Group

Adjunct Associate Professor of Medicine, Emory University School of Medicine



COVID – 19 Vaccines in US under FDA

12/11/2020

12/18/2020

2/27/2021

Pfizer

mRNA BNT 162 b2

VE: 95%

Two doses (0,21)

12 & older* (BLA: ≥16/ EUA: 12-15)

(EUA: additional dose for immunocompromised)

(EUA for "many more"- 9/22/21)

*** reports of myocarditis**

Moderna

mRNA 1273

VE: 94%

Two doses (0,28)

EUA: 18 & older*

(EUA: additional dose for Immunocompromised)

Janssen

Ad26-COV 2 S viral vector

VE (overall): 66.3%

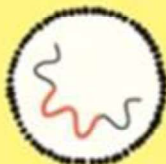
One dose

EUA: 18 & older**

****TTS warning: females <50 / GBS**

Facts about COVID-19 mRNA Vaccines

mRNA



They cannot give someone COVID-19

mRNA vaccines do not use the live virus that causes COVID-19.

They do not affect or interact with our DNA

mRNA never enters the nucleus of the cell, which is where our DNA (genetic material) is kept. The cell breaks down and gets rid of the mRNA soon after it is finished using the instructions.

Source: CDC

FDA's Emergency Use Authorization (EUA) of mRNA COVID 19 vaccines

December 11, 2020:

Pfizer / BioNTech BNT 162 B2 (mRNA)

FDA U.S. FOOD & DRUG ADMINISTRATION

Home / Emergency Preparedness and Response / Pfizer-BioNTech COVID-19 Vaccine

Pfizer-BioNTech COVID-19 Vaccine

On December 11, 2020, the U.S. Food and Drug Administration issued the first emergency use authorization (EUA) for a vaccine for the prevention of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older. The emergency use authorization allows the Pfizer-BioNTech COVID-19 Vaccine to be distributed in the U.S.

Emergency Use Authorization Status: Authorized

Name: Pfizer-BioNTech COVID-19 Vaccine

Manufacturer: Pfizer Inc.

Authorized Use

For the prevention of coronavirus disease (COVID-19) for individuals 16 years of age and older

December 18, 2020:

Moderna 1273 (mRNA)

FDA U.S. FOOD & DRUG ADMINISTRATION

Home / Emergency Preparedness and Response / Moderna COVID-19 Vaccine

FDA Takes Additional Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for Second COVID-19 Vaccine

Action Follows Thorough Evaluation of Available Safety, Effectiveness, and Manufacturing Quality Information by FDA Career Scientists, Input from Independent Experts

For Immediate Release: December 18, 2020

Today, the U.S. Food and Drug Administration issued an emergency use authorization (EUA) for the second vaccine for the prevention of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The emergency use authorization allows the Moderna COVID-19 Vaccine to be distributed in the U.S. for use in individuals 18 years of age and older.

2/27/2021

FDA U.S. FOOD & DRUG ADMINISTRATION

Home / Emergency Preparedness and Response / Counterterrorism and Emerging Threats / Coronavirus Disease 2019 (COVID-19) / Janssen COVID-19 Vaccine

Janssen COVID-19 Vaccine

On February 27, 2021, the U.S. Food and Drug Administration issued an emergency use authorization (EUA) for the third vaccine for the prevention of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). On April 23, 2021, the FDA amended the EUA to include information about a very rare and serious type of blood clot in people who receive the vaccine. The EUA allows the Janssen COVID-19 Vaccine to be distributed in the U.S. for use in individuals 18 years of age and older.

Emergency Use Authorization Status: Authorized

Name: Janssen COVID-19 Vaccine

Manufacturer: Janssen Biotech Inc., a Janssen Pharmaceutical Company of Johnson & Johnson

Authorized Use

For the prevention of coronavirus disease 2019 (COVID-19) for individuals 18 years of age and older

FDA U.S. FOOD & DRUG ADMINISTRATION

Home / Emergency Preparedness and Response / Pfizer-BioNTech COVID-19 Vaccine

1. Pfizer-BioNTech COVID-19 Vaccine

On December 11, 2020, the U.S. Food and Drug Administration issued the first emergency use authorization (EUA) for a vaccine for the prevention of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older. The emergency use authorization allows the Pfizer-BioNTech COVID-19 Vaccine to be distributed in the U.S.

Emergency Use Authorization Status: Authorized

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Manufacturer: Pfizer Inc.

Authorized Use

For the prevention of coronavirus disease (COVID-19) for individuals 16 years of age and older

FDA U.S. FOOD & DRUG ADMINISTRATION

Home / Emergency Preparedness and Response / Moderna COVID-19 Vaccine

2. FDA Takes Additional Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for Second COVID-19 Vaccine

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3.

FDA U.S. FOOD & DRUG ADMINISTRATION

Home / Emergency Preparedness and Response / Counterterrorism and Emerging Threats / Coronavirus Disease 2019 (COVID-19) / Janssen COVID-19 Vaccine

Janssen COVID-19 Vaccine

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Emergency Use Authorization Status: Authorized

Name: Janssen COVID-19 Vaccine

Manufacturer: Janssen Biotech Inc., a Janssen Pharmaceutical Company of Johnson & Johnson

Authorized Use

For the prevention of coronavirus disease 2019 (COVID-19) for individuals 18 years of age and older

Pfizer / BioNTech mRNA vaccine

FDA NEWS RELEASE

FDA Approves First COVID-19 Vaccine

Approval Signifies Key Achievement for Public Health

BLA: 8/23/2021

Full approval for ≥ 16

EUA: age 12-15

EUA: Additional dose

for immunocompromised

Share Tweet LinkedIn Email Print

For Immediate Release: August 23, 2021

Today, the U.S. Food and Drug Administration approved the first COVID-19 vaccine. The vaccine has been known as the Pfizer-BioNTech COVID-19 Vaccine, and will now be marketed as Comirnaty (koe-mir-na-tee), for the prevention of COVID-19 disease in individuals 16 years of age and older. The vaccine also continues to be available under emergency use authorization (EUA), including for individuals 12 through 15 years of age and for the administration of a third dose in certain immunocompromised individuals.

EUA = Emergency Use Authorization ----- BLA = Biologics license application

CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

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COVID-19

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Vaccines

Getting Your Vaccine +

Types of Vaccines Available +

Possible Side Effects

After You're Fully Vaccinated +

Safety & Monitoring +

Effectiveness +

Myths & Facts +

Frequently Asked Questions +

About COVID-19 Vaccines +

Communication Resources +

Possible Side Effects After Getting a COVID-19 Vaccine

Updated Aug. 6, 2021 Languages Print

COVID-19 vaccination will help protect you from getting COVID-19. You may have some side effects, which are normal signs that your body is building protection. These side effects may affect your ability to do daily activities, but they should go away in a few days. Some people have no side effects.

Serious side effects that could cause a long-term health problem are extremely unlikely following any vaccination, including COVID-19 vaccination. Vaccine monitoring has historically shown that side effects generally happen within six weeks of receiving a vaccine dose. For this reason, the FDA required each of the authorized COVID-19 vaccines to be studied for at least two months (eight weeks) after the final dose.

Common Side Effects

On the arm where you got the shot:

- Pain
- Redness
- Swelling

Throughout the rest of your body:

- Tiredness
- Headache
- Muscle pain
- Chills
- Fever
- Nausea

If you had a severe or immediate allergic reaction after getting the first dose of an mRNA COVID-19 vaccine, you should not get a second dose of either of the mRNA COVID-19 vaccines. [Learn about getting a different type of vaccine after an allergic reaction.](#)

Get Email Updates

To receive email updates about COVID-19, enter your email address:

Warnings!

Viral vector vaccine Janssen:

-TTS: Thrombosis with Thrombocytopenia Syndrome (rare)
(more common in women < 50)

-GBS: Guillain-Barre Syndrome (rare)

mRNA vaccines- Pfizer & Moderna

-Myocarditis (heart inflammation)

Excerpt from Prescribing Information for Pfizer mRNA vaccine (Comirnaty):

5 WARNINGS AND PRECAUTIONS

5.2 Myocarditis and Pericarditis

Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The observed risk is higher among males under 40 years of age than among females and older males. The observed risk is highest in males 12 through 17 years of age. Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae. The CDC has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html>).

Myocarditis Risk

- There is risk of myocarditis after COVID mRNA vaccination.
- There is also risk of myocarditis with COVID infection.

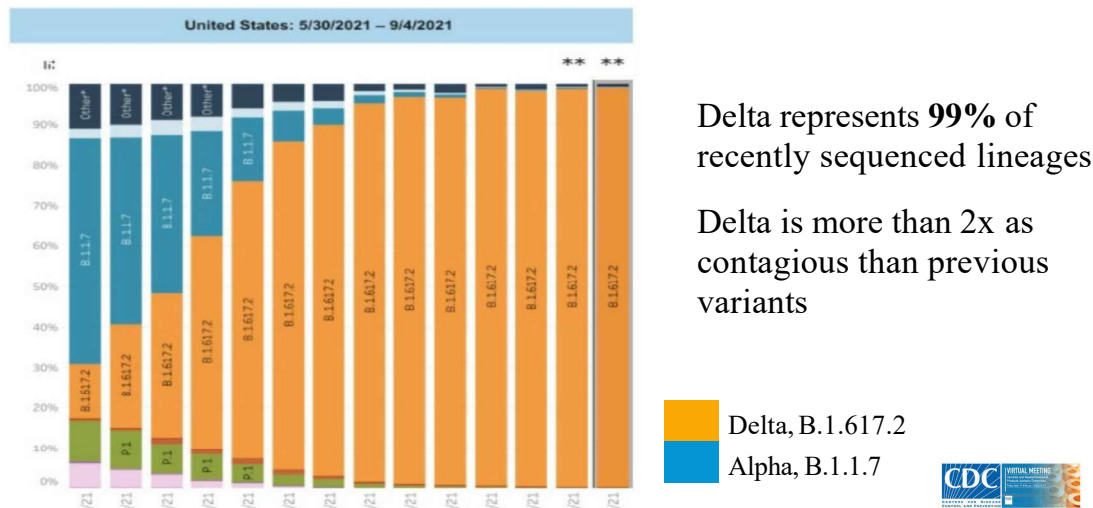
Myocarditis after COVID infection ...occurs at higher rates than after mRNA vaccination!

*Why COVID vaccination
is important
for children and adolescents
(age 12 and older...)*

COVID infections can cause:

**MIS-C (Multisystem inflammatory disorder in children,
Post COVID condition --long haul COVID, Hospitalization , Death**

Delta Is the dominant circulating SARS-CoV-2 variant



<https://covid.cdc.gov/covid-data-tracker/#variant-proportions>; <https://www.cdc.gov/coronavirus/2019-ncov/variants/delta-variant.html>

8

New Recommendation:

Additional vaccine dose for Immunocompromised

Honor System: (no Rx or doctor note needed)



FDA: Emergency Use Authorization (EUA) Amendment

- ➡ **August 12, 2021:** FDA Authorizes Additional Vaccine Dose for Certain Immunocompromised Individuals*
 - Other fully vaccinated individuals do not need an additional dose right now
 - Amendment applies to:
 - **Pfizer-BioNTech** COVID-19 vaccine (BNT162b2) (≥12 years old)
 - **Moderna** COVID-19 vaccine (mRNA-1273) (≥18 years old)
- Due to insufficient data, the EUA amendment for an additional dose does not apply to Janssen COVID-19 vaccine or to individuals who received Janssen COVID-19 as a primary series. CDC and FDA are actively engaged to ensure that immunocompromised recipients of Janssen COVID-19 vaccine have optimal vaccine protection

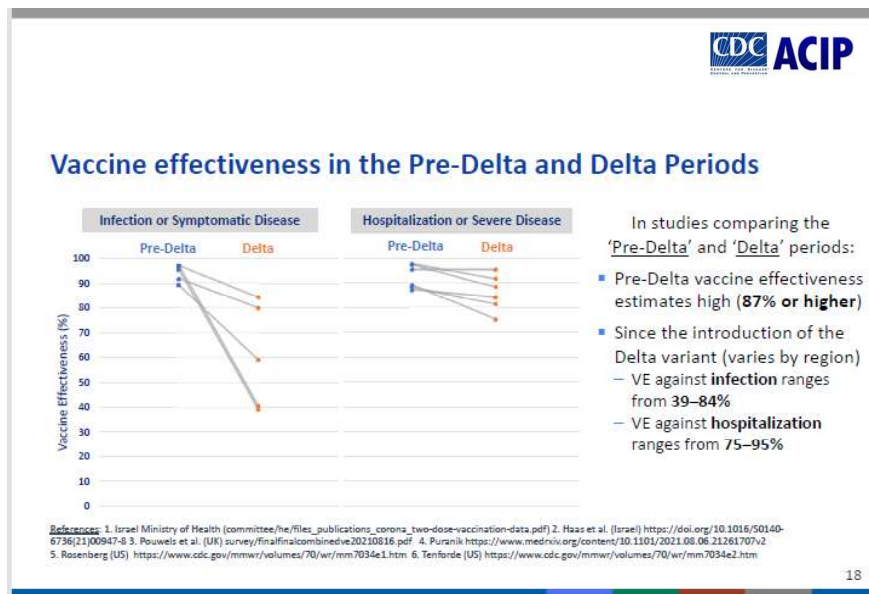
<https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-additional-vaccine-dose-certain-immunocompromised>

Roles of an Additional Dose

There are two distinct potential uses for an additional dose:

- **Additional dose after an initial primary vaccine series:** administration of an additional vaccine dose when the initial immune response following a primary vaccine series is likely to be insufficient.
- **Booster dose:** a dose of vaccine administered when the initial sufficient immune response to a primary vaccine series is likely to have waned over time. The need for and timing of a COVID-19 booster dose have not been established

BOOSTERS? What? When?



FDA expanded Pfizer-BioNTech EUA to include a single booster dose, to be administered at least six months after completion of the primary series in:

- individuals 65 years of age and older;
- individuals 18 through 64 years of age at high risk of severe COVID-19; and
- individuals 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19.

CDC Newsroom

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[Press Materials](#)

CDC Statement on ACIP Booster Recommendations

receive a Pfizer-BioNTech COVID-19 booster shot to help increase their protection.

- **≥ 65**

CDC recommends:

- **Health condition**

- **High exposure job or conditions**

- people 65 years and older and residents in long-term care settings **should** receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series,
- people aged 50–64 years with **underlying medical conditions** **should** receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series,
- people aged 18–49 years with **underlying medical conditions** **may** receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series, based on their individual benefits and risks, and
- people aged 18–64 years who are at increased risk for COVID-19 exposure and transmission because of occupational or institutional setting **may** receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series, based on their individual benefits and risks.

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2021 News Releases

2020 News Releases

2019 News Releases

2018 News Releases

Historical News Releases

[New CDC Data: COVID-19 Vaccination Safe for Pregnant People](#)

[Media Statement](#)

New CDC Data: COVID-19 Vaccination Safe for Pregnant People

Media Statement

For Immediate Release: Wednesday, August 11, 2021
Contact: [Media Relations](#)
(404) 639-3286

CDC has released new data on the safety of the COVID-19 vaccines in pregnant people and is recommending all people 12 years of age and older get vaccinated against COVID-19.

"CDC encourages all pregnant people or people who are thinking about becoming pregnant and those breastfeeding to get vaccinated to protect themselves from COVID-19," said CDC Director Dr. Rochelle Walensky. "The vaccines are safe and effective, and it has never been more urgent to increase vaccinations as we face the highly transmissible Delta variant and see severe outcomes from COVID-19 among unvaccinated pregnant people."

Previously, data from [three safety monitoring systems](#) did not find any safety concerns for pregnant people who were vaccinated late in pregnancy or for their babies. Combined, these data and the known severe risks of COVID-19 during pregnancy demonstrate that the benefits of receiving a COVID-19 vaccine for pregnant people outweigh any known or potential risks.

A [new CDC analysis](#) of current data from the v-safe pregnancy registry assessed vaccination early in pregnancy and did not find an increased risk of miscarriage among nearly 2,500 pregnant women who received an mRNA COVID-19 vaccine before 20 weeks of pregnancy. Miscarriage typically occurs in about 11–16% of pregnancies, and this study found miscarriage rates after receiving a COVID-19 vaccine were around 13%, similar to the expected rate of miscarriage in the general population.



**Some vaccination hesitancy
may be
vaccine inconvenience**

PRESS RELEASES

AMA in support of COVID-19 vaccine mandates for health care workers



JUL 26, 2021

"It is critical that all people in the health care workforce get vaccinated against COVID-19 for the safety of our patients and our colleagues," said Susan R. Bailey, M.D., immediate past president of the American Medical Association. "With more than 300 million doses administered in the United States and nearly 4 billion doses administered worldwide, we know the vaccines are safe and highly effective at preventing severe illness and death from COVID-19. Increased vaccinations among health care personnel will not only reduce the spread of COVID-19 but also reduce the harmful toll this virus is taking within the health care workforce and those we are striving to serve."

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E WHITE HOUSE



Administration Priorities COVID Plan Brief

AP

Sweeping new vaccine mandates for 100 million Americans

10 MINUTE READ

WASHINGTON (AP) — To his about face, President Joe Biden on Thursday ordered sweeping new vaccine mandates for as many as 100 million Americans — a move critics say will do little to curb the virus's spread.

September 9, 2021

PATH OUT OF THE PANDEMIC

PRESIDENT BIDEN'S COVID-19 ACTION PLAN

Requiring All Employers with 100+ Employees to Ensure their Workers are Vaccinated or Tested Weekly



Requiring Vaccinations for all Federal Workers and for Millions of Contractors that Do Business with the Federal Government



Requiring COVID-19 Vaccinations for Over 17 Million Health Care Workers at Medicare and Medicaid Participating Hospitals and Other Health Care Settings



Calling on Large Entertainment Venues to Require Proof of Vaccination or Testing for Entry



Requiring Employers to Provide Paid Time Off to Get Vaccinated



Vaccinating the Unvaccinated

Further Protecting the Vaccinated

Keeping Schools Safely Open

Increasing Testing & Requiring Masking

Protecting Our Economic Recovery

Improving Care for those with COVID-19

The COVID Collaborative

We've assembled a diverse and comprehensive team of leading experts in health, education, and the economy to shape the work of the COVID Collaborative, develop consensus recommendations, and engage with state and local leaders across America — ensuring that our efforts are truly from the nation, for the nation.

ad COUNCIL

COVID Collaborative

About

Language

IT'S UP TO YOU COVID-19 VACCINATION

You have questions about the COVID-19 Vaccines. That's good.

It's normal to be cautious when something new comes along. Wanting to know more is a good thing — it means you want to be informed.

Courtesy of Ad Council



The American Medical Association leads the fight against the COVID-19 pandemic. Here you'll find daily video updates on COVID-19 detailing how we're supporting physicians, medical students and health care workers in this time of crisis.

COVID-19 Daily Video Updates

The American Medical Association leads the fight against the COVID-19 pandemic. Here you'll find daily video updates on COVID-19 detailing how we're supporting physicians, medical students and health care workers in this time of crisis.

Dr. Mitchell Wright on treating post-COVID... 9.7K views • 1 month ago

Dr. Mira Irons on challenges slowing pace of... 500 views • 1 month ago

Dr. Sandra Fryhofer on lifting of J&J vaccine pause... 18K views • 1 month ago

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Vaccine passports: Benefits, challenges and ethical... 7.6K views • 1 month ago

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Prioritizing Equity: Advancing Equity Through... 6.3K views • 1 month ago

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Vaccines & Immunizations

COVID-19 Vaccination

Product info by U.S. Vaccine

Clinical Care

COVID-19 Vaccines

Managing Anaphylaxis

Myocarditis and Pericarditis Considerations

Lab Tests After Severe Allergic Reaction

Vaccinating Homebound Persons

Vaccinating Patients who are Immunocompromised

Jurisdiction: Vaccinating Older Adults and People with Disabilities

Vaccination Sites: Vaccinating Older Adults and People with Disabilities

Provider Requirements and Support

Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States

Reference Materials

Summary Document for Interim Clinical Considerations

Summary Document for Interim Clinical Considerations poster

COVID-19 Vaccine Administration Errors and Deviations

COVID-19 Vaccine Administration Errors and Deviations Poster

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Summary of recent changes (last updated August 31, 2021):

- New Advisory Committee on Immunization Practices (ACIP) recommendation for use of the U.S. Food and Drug Administration (FDA)-approved Pfizer-BioNTech (COMIRNATY) COVID-19 Vaccine in persons aged ≥16 years
- Updated information in Key points to reflect currently available evidence
- Updated information on COVID-19 vaccines in the [Background section](#)
- Updated information in the section on [Considerations for use of an additional dose of COVID-19 vaccine](#) following a primary vaccine series
- Updated [laboratory testing information](#) on timing of immune-based tests for tuberculosis infection in relation to COVID-19 vaccine administration

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

FDA U.S. FOOD & DRUG ADMINISTRATION

FDA NEWS RELEASE

FDA to Hold Advisory Committee Meetings to Discuss Emergency Use Authorization for Booster Doses and COVID-19 Vaccines for Younger Children

VIRTUAL MEETING
Vaccines and Related Biological Products Advisory Committee

**-Oct 14
Moderna
boosters**

On Oct. 14, the committee will discuss an amendment to the emergency use authorization of the [Moderna COVID-19 Vaccine](#) for the administration of a booster dose, in individuals 18 years of age and older.

**-Oct 15
J & J
booster**

On Oct. 15, the VRBPAC will discuss amending the emergency use authorization of Johnson and Johnson's [Janssen COVID-19 Vaccine](#) for the administration of a booster dose, in individuals 18 years of age and older.

**-Mix n'
match
boosters**

Additionally, on Oct. 15, the committee will hear a presentation from the National Institute of Health's National Institute of Allergy and Infectious Diseases on the heterologous use of booster doses following the primary series of the three currently authorized or approved COVID-19 vaccines.

release: October 01, 2021

.S. Food and Drug Administration is announcing two upcoming meetings of and Related Biological Products Advisory Committee (VRBPAC) to discuss le data for the currently available COVID-19 vaccines.

Meeting on Janssen and Moderna COVID-19 Vaccine



??Questions??

END

