From: HHS Office of Public Affairs [HHSOPA@hhs.gov]
Sent: 7/8/2021 8:35:23 PM
To: Commissioner FDA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e55e9a27325472887051a2c7f4f2f88-Commissione]
Subject: Joint CDC and FDA Statement on Vaccine Boosters

News Release

U.S. Department of Health and Human Services

202-690-6343
media@hhs.gov
www.hhs.gov/news
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FOR IMMEDIATE RELEASE
Thursday, July 8, 2021

Joint CDC and FDA Statement on Vaccine Boosters

The United States is fortunate to have highly effective vaccines that are widely available for those aged 12 and up. People who are fully vaccinated are protected from severe disease and death, including from the variants currently circulating in the country such as Delta. People who are not vaccinated remain at risk. Virtually all COVID-19 hospitalizations and deaths are among those who are unvaccinated. We encourage Americans who have not yet been vaccinated to get vaccinated as soon as possible to protect themselves and their community.

Americans who have been fully vaccinated do not need a booster shot at this time. FDA, CDC, and NIH are engaged in a science-based, rigorous process to consider whether or when a booster might be necessary. This process takes into account laboratory data, clinical trial data, and cohort data – which can include data from specific pharmaceutical companies, but does not rely on those data exclusively. We continue to review any new data as it becomes available and will keep the public informed. We are prepared for booster doses if and when the science demonstrates that they are needed.

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From: HHS Office of Public Affairs [HHSOPA@hhs.gov]
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To: Commissioner FDA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e55e9a27325472887051a2c7f4f2f88-Commissione]
Subject: Statement by HHS Secretary Xavier Becerra on COVID-19 Vaccine Booster Doses

News Release

U.S. Department of Health and Human Services

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FOR IMMEDIATE RELEASE
Friday, September 24, 2021

Statement by HHS Secretary Xavier Becerra on COVID-19 Vaccine Booster Doses

Today, Health and Human Services Secretary Xavier Becerra issued the following statement on the significance of booster doses of the Pfizer-BioNTech COVID-19 vaccine reaching millions of eligible people across the country, following decisions made by Food and Drug Administration Acting Commissioner Dr. Janet Woodcock and then Centers for Disease Control and Prevention Director Dr. Rochelle Walensky, respectively.

Earlier this week, after reviewing the data and science from an independent advisory panel to the FDA, Dr. Woodcock amended FDA's emergency-use authorization (EUA) for the Pfizer-BioNTech COVID-19 vaccine to allow a single booster dose, to be administered for individuals 65 years of age and older, as well as in populations at high risk due to underlying medical conditions or due to institutional or occupational exposure, such as health care workers, teachers and prisons. Dr. Walensky's decision today reaffirmed an independent advisory panel's recommendation to the CDC and additionally determined that workers in high-risk jobs should be eligible for boosters, closely aligning with the FDA authorization.

"These decisions by Dr. Woodcock and Dr. Walensky, rooted in data and science, put us on a path to further protect millions of people, get ahead of the COVID-19 pandemic and save lives. Millions of booster doses are available in pharmacies, health departments, clinics and doctor's offices. These booster doses can increase protection, especially for our seniors, people with underlying medical conditions and workers in high-risk environments. Our best chance at turning the tide of the Delta variant is ensuring everyone possible has maximum available protection against COVID-19 infection, severe illness and death. I commend CDC and FDA for their thorough and independent process of evaluating vaccine safety and effectiveness." – Health and Human Services Secretary Xavier Becerra

As Dr. Walensky outlined last night, CDC determined that:

- 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.

Across HHS, we will continue to monitor the safety and efficacy of COVID-19 vaccines in the weeks to come, continuing to evaluate the data and science as it evolves.

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From: HHS Office of Public Affairs [HHSOPA@hhs.gov]
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Subject: Joint Statement from HHS Public Health and Medical Experts on COVID-19 Booster Shots

News Release

U.S. Department of Health and Human Services

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media@hhs.gov
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FOR IMMEDIATE RELEASE
Wednesday, August 18, 2021

Joint Statement from HHS Public Health and Medical Experts on COVID-19 Booster Shots

Today, public health and medical experts from the U.S. Department of Health and Human Services (HHS) released the following statement on the Administration's plan for COVID-19 booster shots for the American people.

The statement is attributable to Dr. Rochelle Walensky, Director of the Centers for Disease Control and Prevention (CDC); Dr. Janet Woodcock, Acting Commissioner, Food and Drug Administration (FDA); Dr. Vivek Murthy, U.S. Surgeon General; Dr. Francis Collins, Director of the National Institutes of Health (NIH); Dr. Anthony Fauci, Chief Medical Advisor to President Joe Biden and Director of the National Institute of Allergy and Infectious Diseases (NIAID); Dr. Rachel Levine, Assistant Secretary for Health; Dr. David Kessler, Chief Science Officer for the COVID-19 Response; and Dr. Marcella Nunez-Smith, Chair of the COVID-19 Health Equity Task Force:

"The COVID-19 vaccines authorized in the United States continue to be remarkably effective in reducing risk of severe disease, hospitalization, and death, even against the widely circulating Delta variant. Recognizing that many vaccines are associated with a reduction in protection over time, and acknowledging that additional vaccine doses could be needed to provide long lasting protection, we have been analyzing the scientific data closely from the United States and around the world to understand how long this protection will last and how we might maximize this protection. The available data make very clear that protection against SARS-CoV-2 infection begins to decrease over time following the initial doses of vaccination, and in association with the dominance of the Delta variant, we are starting to see evidence of reduced protection against mild and moderate disease. Based on our latest assessment, the current protection against severe disease, hospitalization, and death could diminish in the months ahead, especially among those who are at higher risk or were vaccinated during the earlier phases of the vaccination rollout. For that reason, we conclude that a booster shot will be needed to maximize vaccine-induced protection and prolong its durability.

"We have developed a plan to begin offering these booster shots this fall subject to FDA conducting an independent evaluation and determination of the safety and effectiveness of a third dose of the Pfizer and Moderna mRNA vaccines and CDC's Advisory Committee on Immunization Practices (ACIP) issuing booster dose recommendations based on a thorough review of the evidence. We are prepared to offer booster shots for

all Americans beginning the week of September 20 and starting 8 months after an individual's second dose. At that time, the individuals who were fully vaccinated earliest in the vaccination rollout, including many health care providers, nursing home residents, and other seniors, will likely be eligible for a booster. We would also begin efforts to deliver booster shots directly to residents of long-term care facilities at that time, given the distribution of vaccines to this population early in the vaccine rollout and the continued increased risk that COVID-19 poses to them.

"We also anticipate booster shots will likely be needed for people who received the Johnson & Johnson (J&J) vaccine. Administration of the J&J vaccine did not begin in the U.S. until March 2021, and we expect more data on J&J in the next few weeks. With those data in hand, we will keep the public informed with a timely plan for J&J booster shots as well.

"Our top priority remains staying ahead of the virus and protecting the American people from COVID-19 with safe, effective, and long-lasting vaccines especially in the context of a constantly changing virus and epidemiologic landscape. We will continue to follow the science on a daily basis, and we are prepared to modify this plan should new data emerge that requires it.

"We also want to emphasize the ongoing urgency of vaccinating the unvaccinated in the U.S. and around the world. Nearly all the cases of severe disease, hospitalization, and death continue to occur among those not yet vaccinated at all. We will continue to ramp up efforts to increase vaccinations here at home and to ensure people have accurate information about vaccines from trusted sources. We will also continue to expand our efforts to increase the supply of vaccines for other countries, building further on the more than 600 million doses we have already committed to donate globally."

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Americans who have been fully vaccinated do not need a booster shot at this time. FDA, CDC, and NIH are engaged in a science-based, rigorous process to consider whether or when a booster might be necessary. This process takes into account laboratory data, clinical trial data, and cohort data – which can include data from specific pharmaceutical companies, but does not rely on those data exclusively. We continue to review any new data as it becomes available and will keep the public informed. We are prepared for booster doses if and when the science demonstrates that they are needed.

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From: Sams, Ian (HHS/ASPA) [Ian.Sams@hhs.gov]
Sent: 8/18/2021 8:35:56 AM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Walensky, Rochelle P (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df848b046e3947be9b8809afe76917e9-HHS-aux7-cd]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Kessler, David A (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=efb6a7c634694533833de5d2f4beaee3-HHS-David.K]; Nunez-Smith, Marcella (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81cfa45662a14ed090a85d8fcdbf366a-HHS-Marcell]; Levine, Rachel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=14635ebee4ab4367aa606702393a1b78-HHS-Rachel.]; Murthy, Vivek (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0cfbbb11664545269ebc1474542c0779-HHS-Vivek.M]
Subject: Final statement + tough QA
Attachments: Booster statement FINAL 830am.docx

Hey Docs – I wanted to send you the final statement, as well as the comprehensive tough QA, for you this morning.

The statement will be embargoed for 10:30 AM. (I will send it to reporters for that embargo around 9:30 AM.) It will be released widely from HHS just after 10:30. I have worked with your comms directors to align on the rollout plan as well.

Thank you all, and don't hesitate to let me know if I can be helpful with anything,
Ian

Booster statement FINAL 830am.docx

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Ian Sams
Deputy Assistant Secretary for Public Affairs (COVID Response)
U.S. Department of Health and Human Services
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Joint Statement from HHS Public Health and Medical Experts on COVID-19 Booster Shots

Today, public health and medical experts from the U.S. Department of Health and Human Services (HHS) released the following statement on the Administration's plan for COVID-19 booster shots for the American people.

The statement is attributable to Dr. Rochelle Walensky, Director of the Centers for Disease Control and Prevention (CDC); Dr. Janet Woodcock, Acting Commissioner, Food and Drug Administration (FDA); Dr. Vivek Murthy, U.S. Surgeon General; Dr. Francis Collins, Director of the National Institutes of Health (NIH); Dr. Anthony Fauci, Chief Medical Advisor to President Joe Biden and Director of the National Institute of Allergy and Infectious Diseases (NIAID); Dr. Rachel Levine, Assistant Secretary for Health; Dr. David Kessler, Chief Science Officer for the COVID-19 Response; and Dr. Marcella Nunez-Smith, Chair of the COVID-19 Health Equity Task Force:

"The COVID-19 vaccines authorized in the United States continue to be remarkably effective in reducing risk of severe disease, hospitalization, and death, even against the widely circulating Delta variant. Recognizing that many vaccines are associated with a reduction in protection over time, and acknowledging that additional vaccine doses could be needed to provide long lasting protection, we have been analyzing the scientific data closely from the United States and around the world to understand how long this protection will last and how we might maximize this protection. The available data make very clear that protection against SARS-CoV-2 infection begins to decrease over time following the initial doses of vaccination, and in association with the dominance of the Delta variant, we are starting to see evidence of reduced protection against mild and moderate disease. Based on our latest assessment, the current protection against severe disease, hospitalization, and death could diminish in the months ahead, especially among those who are at higher risk or were vaccinated during the earlier phases of the vaccination rollout. For that reason, we conclude that a booster shot will be needed to maximize vaccine-induced protection and prolong its durability.

"We have developed a plan to begin offering these booster shots this fall subject to FDA conducting an independent evaluation and determination of the safety and effectiveness of a third dose of the Pfizer and Moderna mRNA vaccines and CDC's Advisory Committee on Immunization Practices (ACIP) issuing booster dose recommendations based on a thorough review of the evidence. We are prepared to offer booster shots for all Americans beginning the week of September 20 and starting 8 months after an individual's second dose. At that time, the individuals who were fully vaccinated earliest in the vaccination rollout, including many health care providers, nursing home residents, and other seniors, will likely be eligible for a booster. We would also begin efforts to deliver booster shots directly to residents of long-term care facilities at that time, given the distribution of vaccines to this population early in the vaccine rollout and the continued increased risk that COVID-19 poses to them.

"We also anticipate booster shots will likely be needed for people who received the Johnson & Johnson (J&J) vaccine. Administration of the J&J vaccine did not begin in the U.S. until March 2021, and we expect more data on J&J in the next few weeks. With those data in hand, we will keep the public informed with a timely plan for J&J booster shots as well.

"Our top priority remains staying ahead of the virus and protecting the American people from COVID-19 with safe, effective, and long-lasting vaccines especially in the context of a constantly

changing virus and epidemiologic landscape. We will continue to follow the science on a daily basis, and we are prepared to modify this plan should new data emerge that requires it.

"We also want to emphasize the ongoing urgency of vaccinating the unvaccinated in the U.S. and around the world. Nearly all the cases of severe disease, hospitalization, and death continue to occur among those not yet vaccinated at all. We will continue to ramp up efforts to increase vaccinations here at home and to ensure people have accurate information about vaccines from trusted sources. We will also continue to expand our efforts to increase the supply of vaccines for other countries, building further on the more than 600 million doses we have already committed to donate globally."

TOUGH Q&A

PROCESS

How can you make this decision ahead of FDA authorizing boosters, or CDC formally recommending them?

- We know that people who have been fully vaccinated have had questions about when or whether they may need a booster shot.
- As we have always said, we are going to be clear and transparent with the public with what we know when we know it.
- The data available are clear that boosters will likely be needed to optimize protection against the virus, recognizing that many vaccines are associated with a reduction in protection over time, and we want to be clear to the public that we are prepared to begin boosting at the 8-month mark after individuals receive their second dose, pending FDA review/authorization/approval and any CDC recommendations.

Why are you making this decision when you have no concrete data that the risk of hospitalization is increasing amongst the vaccinated?

- We are seeing the effectiveness of our vaccines wane over time and against the Delta variant.
- Also, we are hearing from other countries who are further along than us that they are seeing their hospitalization rates amongst those who have been vaccinated since early this year go up.
- We have to stay ahead of this. Therefore, we are making the clinical judgement that a reasonable time frame to start a boosting program is 8 months to ensure maximum protection.

Why are you planning to give a booster to <u>ALL</u> Americans, not just seniors or the most vulnerable? This is different than what we have seen in other countries.

- This is a constantly evolving virus, especially with the prevalence of new variants including Delta, which has only been widely circulating in the U.S. for six weeks.
- We are looking at all data available from the U.S. and around the world to understand as much of the information on vaccine effectiveness as we can.
- While protection against hospitalizations seems to be holding at this point, we are concerned that this protection against severe disease could diminish in the months ahead, especially among those who were vaccinated first. We want to stay ahead of the virus and make these plans to protect people before that happens.
- Based on the available data, we believe we can start boosting people at their 8-month mark from receiving their second dose to increase protection against the potential for waning effectiveness against severe disease, hospitalization, and death, which could begin diminishing in the months ahead.
- This is important not only to protect the most vulnerable, but also to ensure extended protection that can lower the risk of transmission and better control the pandemic.

Why aren't you starting with the most vulnerable?

- We are.
- The first people eligible at the 8-month mark will be those who were in line first to receive their shots in the initial vaccine rollout, including nursing home and long-term care residents, health care workers, and other vulnerable populations.

Why aren't we boosting seniors or nursing home residents <u>now</u>?

- At this time, all the safety data has not been submitted or reviewed.
- We believe boosts will be needed, but we are setting forth a plan starting at 8 months after second dose.
- We are encouraging states to follow the FDA and CDC review and recommendations closely and prepare for boosts along the timeline we are setting forward, to ensure compatibility with legal and regulatory actions prior to implementation.

When will the FDA approve booster shots?

- The FDA will review the data submitted by the vaccine manufacturers and other available data and determine whether they meet the standards for safety and effectiveness to authorize or approve an additional dose of the vaccines.
- Assuming this data is submitted in a timely manner, we anticipate review of these submissions could be completed before the end of September.

Why are we boosting adults before kids have <u>any</u> vaccine? Shouldn't FDA be prioritizing kids?

- FDA has already authorized Pfizer vaccine for adolescents age 12-17. FDA is currently evaluating the Moderna application for authorizing vaccines for that same group.
- We also know that there are ongoing trials evaluating the effectiveness of the vaccines for kids under 12.
- FDA will review these data once they are submitted and will make its determination accordingly.
- Moving forward with boosters does not in any way limit or delay when our kids are vaccinated.

TIME FRAME / 8 MONTHS

How did you land at 8 months until people should get a booster?

- We are looking at all data available from the U.S. and around the world to understand as much of the information on vaccine effectiveness as we can.
- While we are seeing evidence of reduced protection against mild and moderate disease, protection against hospitalization and severe outcomes seems to be holding well at this point.
- Based on the data available, we believe we can start boosting people at their 8-month mark from receiving their second dose to increase protection against the potential for waning effectiveness against severe disease, hospitalization, and death, which could begin diminishing in the months ahead.

If an 8-month interval is being recommended, why will the program not begin until late September? Millions of people - primarily healthcare workers and LTC residents - will be due or overdue for a shot by then.

- We are looking at all data available from the U.S. and around the world to understand as much of the information on vaccine effectiveness as we can.
- While we are seeing evidence of reduced protection against mild and moderate disease, protection against hospitalization and severe outcomes seems to be holding well at this point.
- Based on the data available, we believe we can start boosting people at their 8-month mark from receiving their second dose to increase protection against the potential for waning effectiveness against severe disease, hospitalization, and death, which could begin diminishing in the months ahead.

Why are we waiting to start boosting? Some data shows that vaccine effectiveness wanes as early as 6 months after getting vaccinated.

- This is a constantly evolving virus, especially with the prevalence of new variants including Delta, which has only been widely circulating in the U.S. for six weeks.

- We are looking at all data available from the U.S. and around the world to understand as much of the information on vaccine effectiveness as we can.
- While we are seeing evidence of reduced protection against mild and moderate disease, protection against hospitalization and severe outcomes seems to be holding well at this point.
- Based on the data available, we believe we can start boosting people at their 8-month mark from receiving their second dose to increase protection against the potential for waning effectiveness against severe disease, hospitalization, and death, which could begin diminishing in the months ahead.

J&J

Will people who received the J&J vaccine need a booster shot?

- We believe boosters will likely be needed for people who received the J&J vaccine.
- Administration of the J&J vaccine did not begin in the U.S. until March 2021 (about 70 days after the first Pfizer doses were administered), and we expect more data on J&J in the next few weeks.
- When we have those data in hand, we will provide additional details on booster shots for J&J recipients.

Can people who received the J&J vaccine get a boost of an mRNA vaccine?

- There is currently no data to support mixing the J&J vaccine with either a Pfizer or Moderna boost, so we cannot recommend that at this time.
- We do believe people who have received J&J will likely need a booster shot, and we are expecting more data from J&J in the next few weeks.
- We will provide additional details on booster shots for J&J recipients based on that data.

POPULATIONS

What about 16-17 year olds?

- FDA will review data on boosters among adolescents/minors and make that determination.

Why are residents of Long Term Care Facilities being prioritized for boosters?

- Our top priority is saving lives, and residents of LTC facilities have been disproportionately impacted by severe outcomes due to COVID-19.
- Given the concern that vaccine efficacy wanes over time, this is also the group that received doses early, so it makes sense for them to be at the top of the list.
- We will begin efforts to deliver booster shots directly to residents of LTC facilities starting in late September.
- This will help ensure this at-risk population has increased protection as we carry out the booster campaign.

GLOBAL

Given that we will not end the pandemic unless more people around the world get vaccinated, should we not be delaying boosters here so we can send more abroad?

- As always, we are continuing to serve as an arsenal of vaccines for the world – we have committed to giving away more than half a billion doses globally. The U.S. has already donated more than 110 million doses to more than 60 countries, more than any other nation on earth. Hundreds of millions more are starting to ship this month.
- We can protect Americans who need additional doses to stay safe from COVID-19 while also continuing to increase global access to vaccines.

SCIENCE / MEDICAL

What is the link between waning vaccine effectiveness and the actual <u>need</u> for a booster? Just because protection has dropped below 90% effectiveness, does that really mean you need a booster?

- We are analyzing all available data, and it's becoming clear that vaccine-induced protection against infection does begin to decrease over time, and in association with the dominance of the Delta variant, we are starting to see evidence of reduced protection against mild and moderate disease.
- While protection against hospitalizations seems to be holding at this point, we are concerned that this protection against severe disease could diminish in the months ahead, especially among those who were vaccinated first. We want to stay ahead of the virus and make these plans to protect people before that happens.
- For that reason, we believe people will need a booster shot to increase their protection.

Is there any reason not to get a booster shot?

- The data available is clear that boosters will likely be needed to optimize protection against the virus, recognizing that most vaccines experience a reduction in protection over time, and we want to be clear to the public that we are prepared to begin boosting at the 8-month mark after individuals receive their second dose, pending FDA authorization and any formal CDC recommendations.

Are you seeing more breakthrough cases now? What is the rate?

- The most infection, the most severe disease, and the most transmission is occurring among those who are unvaccinated.
- However, the data is showing more breakthrough cases now than we saw in the spring, and the vast majority continue to be mild or asymptomatic.
- Some of this is to be expected: As more people are vaccinated, the absolute number of cases among those who are vaccinated will increase.
- But increases in cases among the vaccinated also likely reflect what we have been saying: the available data make clear that vaccine-induced protection against infection does begin to decrease over time, and in association with the dominance of the Delta variant, we are starting to see evidence of reduced protection against mild and moderate disease in certain populations. That's why we are prepared to begin offering booster shots next month.

What is the new rate of breakthrough hospitalizations?

- The most infection, the most severe disease, and the most transmission is occurring among those who are unvaccinated.
- However, we are seeing evidence of reduced protection against mild and moderate disease, protection against hospitalization and severe outcomes seems to be holding well at this point.
- Unvaccinated adults are 14.5-times more likely to be hospitalized than vaccinated adults.
- But even vaccine-induced protection against severe disease, hospitalization, and death could diminish in the months ahead, especially among those who were vaccinated during the earlier phases of the vaccination rollout.
- For that reason, we conclude that a booster shot will be needed to maximize vaccine-induced protection.

What do you know now about breakthrough rates that you didn't know before?

- The available data including new CDC data from multiple studies, all with data in the context of the Delta variant, make very clear that vaccine-induced protection against SARS-CoV-2 infection does begin to decrease over time, and in association with the dominance of the Delta variant, we are starting to see evidence of reduced protection against mild and moderate disease in certain populations.
- While we are seeing evidence of reduced protection against mild and moderate disease, protection against hospitalization and severe outcomes seems to be holding well at this point.
- Looking at all the data available, we are concerned that this protection against severe disease, hospitalization, and death could diminish in the months ahead, especially among those who were vaccinated during the earlier phases of the vaccination rollout.
- For that reason, we conclude that an additional late booster will be needed to maximize vaccine-induced protection.

Based on the data available, do recipients of the Moderna vaccine have higher protection? Data seem to suggest it is holding up better in terms of protection. Do Moderna recipients need a booster on the same time frame as those who received Pfizer?

- The available data make very clear that vaccine-induced protection against SARS-CoV-2 infection does begin to decrease over time, including with Moderna.
- While we are seeing evidence of reduced protection against mild and moderate disease, protection against hospitalization and severe outcomes seems to be holding well at this point.
- Looking at all the data available, we are concerned that this protection against severe disease, hospitalization, and death could diminish in the months ahead, especially among those who were vaccinated during the earlier phases of the vaccination rollout.
- For that reason, we conclude that a booster shot will be needed to maximize vaccine-induced protection, including for Moderna recipients.

LONG-TERM / OPERATIONAL

When will I need another shot after my booster? Will boosters be required annually?

- This is a constantly evolving virus, and we will be continually analyzing the data as it becomes available to make decisions about the future.
- There is no data available yet for a long-term time horizon like that.
- At this time, the evidence shows individuals will need a booster shot of an additional dose, starting 8 months after receiving their second dose.

Does your booster shot need to be the same brand as the original vaccine you received, or can you mix and match?

- Individuals should receive a boost of the same vaccine they originally received.
- We will continue to analyze new data, including on the possibility of switching vaccines, as it becomes available.

Do you have to get your booster within the time frame to be considered "fully vaccinated"?

- As part of any formal recommendations by ACIP, they will discuss the data around boosters and outline what the recommendation is to be considered fully vaccinated.

Are we changing verification process?

- No. As we have said, there will be no federal vaccinations database.
- Vaccine credentialing systems should meet key standards on:
    - Affordability
    - Digitally and on paper
    - Protecting people's privacy and security.

What do you do if you've lost your CDC vaccine card? How would providers know it's been 8 months since you've been vaccinated?

- The jurisdiction where you got vaccinated as well as the provider who vaccinated should have processes in place to verify when you were vaccinated.

Will you get a new vaccine card?

- All vaccine recipients should have received a CDC vaccination card when they were initially vaccinated.
- If you have your card from your first two doses, please bring it and have your third dose added (there are two additional spaces on the card).
- If you have lost your original card, you will be provided a new one.

Can you get a booster at the same place you got your original vaccine?

- Booster shots will be convenient and accessible. Vaccines will be available at pharmacies, in primary care provider offices, and health departments may set up vaccination centers.

Will there be mass vaccination sites set up?

- Booster shots will be convenient and accessible. Vaccines will be available at pharmacies, in primary care provider offices, and health departments may set up additional vaccination sites.
- FEMA will be ready to support vaccination efforts as needed.

What should the more than 1M people who have gone ahead and gotten an additional dose do?

- This is a small percentage – less than 1% - of people who have been vaccinated.
- ACIP will make formal recommendations about booster doses, but at this point if you have already received a third dose, please talk to your health care provider.

Are individuals who missed their second dose eligible for a booster?

- If you missed your second dose, you should go get it right away.

From: Tierney, Julia [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1160D300BC4248B790DED292A082E9A8-JULIA.TIERN]
Sent: 9/27/2021 10:39:09 AM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
Subject: FW: Secretarial Directive on Eligibility to Receive Particular COVID-19 Vaccine Boosters
Attachments: Final HHS Secretarial Directive September 25 2021.pdf

FYI

From: Pearlman, Aj (HHS/IOS) <Aj.Pearlman@hhs.gov>
Sent: Monday, September 27, 2021 10:37 AM
To: Fenton, Robert (DHS.GOV) <robert.fenton@fema.dhs.gov>; mzlong@bop.gov; Michael Crockett <mcrockett@bop.gov>; Zachary (BOP) Kelton <Zachary.Kelton@usdoj.gov>; Katz, Rebecca (state.gov) <katzrl@state.gov>; Bibo, David (fema.dhs.gov) <David.Bibo@fema.dhs.gov>; Nair, Suma (HRSA) <SNair1@hrsa.gov>; Macrae, Jim (HRSA) <JMacrae@hrsa.gov>; Alvarez, Kathryn (OS) <Kathryn.Alvarez@hhs.gov>; Bratcher-Bowman, Nikki (OS) <nikki.bratcherbowman@hhs.gov>; OS Criswell, Deanne <Deanne.Criswell@fema.dhs.gov>; Adirim, Terry A SES OSD OUSD P-R (USA) <(b) (6) @mail.mil>; OS Criswell, Deanne <Deanne.Criswell@fema.dhs.gov>; Criswell, D (fema.dhs.gov) <d.criswell@fema.dhs.gov>; Nguyen, Eric (ODAG) <Eric.Nguyen2@usdoj.gov>
Cc: O'Connell, Dawn (OS) <Dawn.Oconnell@hhs.gov>; natalie.h.quillian (eop.gov) <(b) (6) @who.eop.gov>; Cc: Sackner-Bernstein, Sonya E. EOP/WHO <(b) (6) @who.eop.gov>; Mohiuddin, Syed (OS) <Syed.Mohiuddin@hhs.gov>; Sams, Ian C (OS) <Ian.Sams@hhs.gov>; Daskalakis, Demetre C (CDC) <yzq5@cdc.gov>; Romanik, Nikki J (CDC) <kon6@cdc.gov>; Berger, Sherri (CDC) <sob8@cdc.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Espinosa, Kimberly (OS) <Kimberly.Espinosa@hhs.gov>
Subject: Secretarial Directive on Eligibility to Receive Particular COVID-19 Vaccine Boosters

Colleagues,

Following up on the COVID-19 Deputies Meeting this morning, we wanted to make you aware of Secretary Becerra's Directive, which provides:

As of September 25, 2021, all CDC COVID-19 Vaccination Program enrolled providers shall make immediately available and administer a booster dose of PfizerBioNTech COVID-19 vaccine to any and all individuals seeking such a dose who have completed their primary series of Pfizer-BioNTech COVID-19 vaccine at least six months ago and (1) who are 65 years or older; (2) who are 18 years or older and are residents in long term care settings; (3) who are 18 years or older with underlying medical conditions as described in CDC clinical guidance and in accordance with the CDCs recommendation3 ; or (4) who are 18 years or older with increased risk of getting COVID-19 disease due to occupational or institutional exposure, such as frontline essential workers and healthcare workers4 as described in and in accordance with CDC's recommendation.

All enrolled providers in the COVID-19 Vaccination Program (including federal jurisdiction partners) must comply with the Secretarial Directive, which is attached and can be found online at https://www.hhs.gov/sites/default/files/secretarial-directive-eligibility-covid-19-vaccine-boosters.pdf.

Please don't hesitate to reach out if you have any questions.

Thanks,
AJ

From: Pearlman, Aj (HHS/IOS)
Sent: Friday, September 24, 2021 8:00 AM
To: Fenton, Robert (DHS.GOV) <robert.fenton@fema.dhs.gov>; mzlong@bop.gov; Michael Crockett <mcrockett@bop.gov>; Zachary (BOP) Kelton <Zachary.Kelton@usdoj.gov>; Katz, Rebecca (state.gov) <katzrl@state.gov>; Bibo, David (fema.dhs.gov) <David.Bibo@fema.dhs.gov>; Nair, Suma (HRSA) <SNair1@hrsa.gov>; Macrae, Jim (HRSA) <JMacrae@hrsa.gov>; Alvarez, Kathryn (OS/ASPR/IO) <Kathryn.Alvarez@hhs.gov>; Bratcher-Bowman, Nikki (OS/ASPR/IO) <nikki.bratcherbowman@hhs.gov>; OS Criswell, Deanne <Deanne.Criswell@fema.dhs.gov>; Adirim, Terry A SES OSD OUSD P-R (USA) <(b) (6) @mail.mil>; OS Criswell, Deanne <Deanne.Criswell@fema.dhs.gov>; Criswell, D (fema.dhs.gov) <d.criswell@fema.dhs.gov>; Nguyen, Eric (ODAG) <Eric.Nguyen2@usdoj.gov>
Cc: O'Connell, Dawn (OS/ASPR/IO) <Dawn.Oconnell@hhs.gov>; natalie.h.quillian (eop.gov) <(b) (6) @who.eop.gov>; Cc: Sackner-Bernstein, Sonya E. EOP/WHO <(b) (6) @who.eop.gov>; Mohiuddin, Syed (OS/IOS) <Syed.Mohiuddin@hhs.gov>; Sams, Ian (HHS/ASPA) <Ian.Sams@hhs.gov>; Daskalakis, Demetre (CDC/DDID/NCHHSTP/DHP) <yzq5@cdc.gov>; Romanik, Nikki Jo (CDC/OD/OCS) <kon6@cdc.gov>; Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>; Tierney, Julia (FDA/OC) <Julia.Tierney@fda.hhs.gov>; Espinosa, Kimberly (HHS/ASL) <Kimberly.Espinosa@hhs.gov>
Subject: CDC Statement on ACIP Booster Recommendations

Dear Colleagues,

We want to be sure that you saw the statement released by CDC last night. People who got Pfizer and are ages 65 and older, at high risk for severe COVID, or work in a high risk job can now go get their booster, starting at least 6 months after their 2nd shot. This is an important step for millions of Americans to get a booster shot. This is the first group of people eligible, and FDA and CDC will continue to evaluate data over the coming weeks to make determinations for additional populations going forward, including those who have received Moderna or Johnson & Johnson vaccine. CDC's statement is below.

Please do not hesitate to reach out if you have any questions – thank you so much for your partnership to get people vaccinated as we all work to end the pandemic.

Best,
AJ

AJ Pearlman
Chief of Staff, COVID-19 Response
Department of Health and Human Services
AJ.Pearlman@hhs.gov

CDC Statement on ACIP Booster Recommendations

Today, CDC Director Rochelle P. Walensky, M.D., M.P.H., endorsed the CDC Advisory Committee on Immunization Practices' (ACIP) recommendation for a booster shot of the Pfizer-BioNTech COVID-19 vaccine in certain populations and also recommended a booster dose for those in high risk occupational and institutional settings. The Food and Drug Administration's (FDA) authorization and CDC's guidance for use are important steps forward as we work to stay ahead of the virus and keep Americans safe.

This updated interim guidance from CDC allows for millions of Americans who are at highest risk for COVID-19 to receive a Pfizer-BioNTech COVID-19 booster shot to help increase their protection.

CDC recommends:

- 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.

Many of the people who are now eligible to receive a booster shot received their initial vaccine early in the vaccination program and will benefit from additional protection. With the Delta variant's dominance as the circulating strain and cases of COVID-19 increasing significantly across the United States, a booster shot will help strengthen protection against severe disease in those populations who are at high-risk for exposure to COVID-19 or the complications from severe disease.

CDC will continue to monitor the safety and effectiveness of COVID-19 vaccines to ensure appropriate recommendations to keep all Americans safe. We will also evaluate with similar urgency available data in the coming weeks to swiftly make additional recommendations for other populations or people who got the Moderna or Johnson & Johnson vaccines.

The following is attributable to Dr. Walensky:

As CDC Director, it is my job to recognize where our actions can have the greatest impact. At CDC, we are tasked with analyzing complex, often imperfect data to make concrete recommendations that optimize health. In a pandemic, even with uncertainty, we must take actions that we anticipate will do the greatest good.

I believe we can best serve the nation's public health needs by providing booster doses for the elderly, those in long-term care facilities, people with underlying medical conditions, and for adults at high risk of disease from occupational and institutional exposures to COVID-19. This aligns with the FDA's booster authorization and makes these groups eligible for a booster shot. Today, ACIP only reviewed data for the Pfizer-BioNTech vaccine. We will address, with the same sense of urgency, recommendations for the Moderna and J&J vaccines as soon as those data are available.

While today's action was an initial step related to booster shots, it will not distract from our most important focus of primary vaccination in the United States and around the world. I want to thank ACIP for their thoughtful discussion and scientific deliberation on the current data which informed my recommendation.

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

CDC works 24/7 protecting America's health, safety and security. Whether disease start at home or abroad, are curable or preventable, chronic or acute, or from human activity or deliberate attack, CDC responds to America's most pressing health threats. CDC is headquartered in Atlanta and has experts located throughout the United States and the world.

From: Pearlman, Aj (HHS/IOS)
Sent: Wednesday, September 22, 2021 8:27 PM
To: Fenton, Robert (DHS.GOV) <robert.fenton@fema.dhs.gov>; mzlong@bop.gov; Michael Crockett <mcrockett@bop.gov>; Zachary (BOP) Kelton <Zachary.Kelton@usdoj.gov>; Katz, Rebecca (state.gov) <katzrl@state.gov>; Bibo, David (fema.dhs.gov) <David.Bibo@fema.dhs.gov>; Nair, Suma (HRSA) <SNair1@hrsa.gov>; Macrae, Jim (HRSA) <JMacrae@hrsa.gov>; Alvarez, Kathryn (OS/ASPR/IO) <Kathryn.Alvarez@hhs.gov>; Bratcher-Bowman, Nikki (OS/ASPR/IO) <nikki.bratcherbowman@hhs.gov>; eric.nguyen2@doj.gov; OS Criswell, Deanne <Deanne.Criswell@fema.dhs.gov>; Adirim, Terry A SES OSD OUSD P-R (USA) <(b) (6) @mail.mil>

Cc: O'Connell, Dawn (OS/ASPR/IO) <Dawn.Oconnell@hhs.gov>; natalie.h.quillian (eop.gov) (b) (6) @who.eop.gov>; Cc: Sackner-Bernstein, Sonya E. EOP/WHO <(b) (6) @who.eop.gov>; Mohiuddin, Syed (OS/IOS) <Syed.Mohiuddin@hhs.gov>; Sams, Ian (HHS/ASPA) <Ian.Sams@hhs.gov>; Daskalakis, Demetre (CDC/DDID/NCHHSTP/DHP) <yzq5@cdc.gov>; Romanik, Nikki Jo (CDC/OD/OCS) <kon6@cdc.gov>; Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>; Tierney, Julia (FDA/OC) <Julia.Tierney@fda.hhs.gov>
Subject: FDA Authorizes Booster Dose of Pfizer-BioNTech COVID-19 Vaccine for Certain Populations

Dear Colleagues,

On behalf of HHS Assistant Secretary for Preparedness and Response Dawn O'Connell, I want to be sure that you and your teams are aware of the news that the FDA has authorized booster doses for Pfizer for certain populations (as noted below). This is an important step forward, and CDC's Advisory Committee on Immunization Practices (ACIP) will meet tomorrow to discuss FDA's decision and provide clinical recommendations. We will be sure to update you following the ACIP meeting on next steps.

Thanks to all of you for your continued efforts to get Americans vaccinated as we work to end this pandemic. If you or your colleagues have any questions, please don't hesitate to be in touch.

Best,

AJ

AJ Pearlman
Chief of Staff, COVID-19 Response
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FDA Authorizes Booster Dose of Pfizer-BioNTech COVID-19 Vaccine for Certain Populations

Today, the U.S. Food and Drug Administration amended the emergency use authorization (EUA) for the Pfizer-BioNTech COVID-19 Vaccine to allow for use of 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.

Today's authorization applies only to the Pfizer-BioNTech COVID-19 Vaccine.

"Today's action demonstrates that science and the currently available data continue to guide the FDA's decision-making for COVID-19 vaccines during this pandemic. After considering the totality of the available scientific evidence and the deliberations of our advisory committee of independent, external experts, the FDA amended the EUA for the Pfizer-BioNTech COVID-19 Vaccine to allow for a booster dose in certain populations such as health care workers, teachers and day care staff, grocery workers and those in homeless shelters or prisons, among others," said Acting FDA Commissioner Janet Woodcock, M.D. "This pandemic is dynamic and evolving, with new data about vaccine safety and effectiveness becoming available every day. As we learn more about the safety and effectiveness of COVID-19 vaccines, including the use of a booster dose, we will continue to evaluate the rapidly changing science and keep the public informed."

The Process for Assessing the Available Data

Comirnaty (COVID-19 Vaccine, mRNA), was approved by the FDA on Aug. 23, for the prevention of COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older. On Aug. 25, 2021, the FDA received a supplement from Pfizer Inc. to their biologics license application for Comirnaty seeking approval of a single booster dose to be administered approximately six months after completion of the primary vaccination series for individuals 16 years of age and older.

As part of the FDA's commitment to transparency, the agency convened a public meeting of its Vaccines and Related Biological Products Advisory Committee (VRBPAC) on Sept. 17 to solicit input from independent scientific and public health experts on the data submitted in the application. During the meeting, the vaccine manufacturer presented information and data in support of its application. The FDA also presented its analysis of clinical trial data submitted by the vaccine manufacturer. Additionally, the public was also given an opportunity to provide comment; and FDA invited international and U.S. agencies and external groups, including representatives from the Israeli Ministry of Health, the University of Bristol, U.K. and the Centers for Disease Control and Prevention, to present recent data on the use of vaccine boosters, epidemiology of COVID-19, and real-world evidence on vaccine effectiveness.

The FDA considered the data that the vaccine manufacturer submitted, information presented at the VRBPAC meeting, and the committee's discussion, and has determined that based on the totality of the available scientific evidence, a booster dose of Pfizer-BioNTech COVID-19 Vaccine may be effective in preventing COVID-19 and that the known and potential benefits of a booster dose outweigh the known and potential risks in the populations that the FDA is authorizing for use. The booster dose is authorized for administration to these individuals at least six months following completion of their primary series and may be given at any point after that time.

It's important to note that the FDA-authorized Pfizer-BioNTech COVID-19 Vaccine is the same formulation as the FDA-approved Comirnaty and the vaccines may be used interchangeably.

"We're grateful for the advice of the doctors, scientists, and leading vaccine experts on our advisory committee and the important role they have played in ensuring transparent discussions about COVID-19 vaccines. We appreciate the robust discussion, including the vote regarding individuals over 65 years of age and individuals at high risk for severe disease, as well as the committee's views regarding the use of a booster dose for those with institutional or occupational exposure to SARS-CoV-2," said Peter Marks, M.D., Ph.D., director of FDA's Center for Biologics Evaluation and Research. "The FDA considered the committee's input and conducted its own thorough review of the submitted data to reach today's decision. We will continue to analyze data submitted to the FDA pertaining to the use of booster doses of COVID-19 vaccines and we will make further decisions as appropriate based on the data."

Data Supporting Authorization for Emergency Use

To support the authorization for emergency use of a single booster dose, the FDA analyzed safety and immune response data from a subset of participants from the original clinical trial of the Pfizer-BioNTech COVID-19 Vaccine. In addition, consideration was given to real-world data on the vaccine's efficacy over a sustained period of time provided by both U.S. and international sources, including the CDC, the UK and Israel. The immune responses of approximately 200 participants 18 through 55 years of age who received a single booster dose approximately six months after their second dose were assessed. The antibody response against SARS-CoV-2 virus one month after a booster dose of the vaccine compared to the response one month after the two-dose primary series in the same individuals demonstrated a booster response.

Additional analysis conducted by the manufacturer, as requested by the FDA, compared the rates of COVID-19 accrued during the current Delta variant surge among original clinical trial participants

who completed the primary two-dose vaccination series early in the clinical trial to those who completed a two-dose series later in the study. The analysis submitted by the company showed that during the study period of July and August 2021, the incidence of COVID-19 was higher among the participants who completed their primary vaccine series earlier, compared to participants who completed it later. The FDA determined that the rate of breakthrough COVID-19 reported during this time period translates to a modest decrease in the efficacy of the vaccine among those vaccinated earlier.

Safety was evaluated in 306 participants 18 through 55 years of age and 12 participants 65 years of age and older who were followed for an average of over two months. The most commonly reported side effects by the clinical trial participants who received the booster dose of the vaccine were pain, redness and swelling at the injection site, as well as fatigue, headache, muscle or joint pain and chills. Of note, swollen lymph nodes in the underarm were observed more frequently following the booster dose than after the primary two-dose series.

Since Dec. 11, 2020, the Pfizer-BioNTech COVID-19 Vaccine has been available under EUA for individuals 16 years of age and older. The authorization was expanded on May 20, 2021 to include those 12 through 15 years of age, and again on Aug. 12, 2021 to include the use of a third dose of a three-dose primary series in certain immunocompromised individuals 12 years of age and older. EUAs can be used by the FDA during public health emergencies to provide access to medical products that may be effective in preventing, diagnosing, or treating a disease, provided that the FDA determines that the known and potential benefits of a product, when used to prevent, diagnose, or treat the disease, outweigh the known and potential risks of the product.

The amendment to the EUA to include a single booster dose was granted to Pfizer Inc.

https://www.fda.gov/news-events/press-announcements/fda-authorizes-booster-dose-pfizer-biontech-covid-19-vaccine-certain-populations

SECRETARIAL DIRECTIVE ON ELIGIBILITY TO RECEIVE PARTICULAR COVID-19 VACCINE BOOSTERS

September 25, 2021

The Centers for Disease Control and Prevention (CDC) has determined that, as part of the broad range of prevention and mitigation strategies, "[v]accines are an important tool to help stop the COVID-19 pandemic.[1]" To that end, CDC has continued to consider available science, including SARS-CoV-2 epidemiology, evidence related to the effectiveness of currently available Food and Drug Administration (FDA) approved or authorized COVID-19 vaccines, and any risks of severe disease, hospitalization, and death to certain populations.

On September 22, 2021, FDA amended the emergency use authorization (EUA) for the Pfizer-BioNTech COVID-19 Vaccine to allow for use of a single booster dose, to be administered at least six months after completion of the Pfizer-BioNTech COVID-19 vaccine primary series in: individuals 65 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.

Based on CDC's review of the available data, and taking into account data and information that were presented to and considered by the Advisory Committee on Immunization Practices (ACIP), the Director of the CDC[2] recommended that: people 65 years and older and residents in long-term care settings18 years or older should receive a booster shot of Pfizer-BioNTech COVID-19 vaccine at least six months after their Pfizer-BioNTech COVID-19 vaccine primary series; people aged 50–64 years with underlying medical conditions should receive a booster shot of Pfizer-BioNTech COVID-19 vaccine at least six months after their Pfizer-BioNTech COVID-19 vaccine primary series; people aged 18–49 years with underlying medical conditions may receive a booster shot of Pfizer-BioNTech COVID-19 vaccine at least six months after their Pfizer-BioNTech COVID-19 vaccine 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 COVID-19 vaccine at least six months after their Pfizer-BioNTech COVID-19 vaccine primary series, based on their individual benefits and risks.

The Department of Health and Human Services (HHS) concurs with CDC's recommendation. Accordingly, pursuant to Section 319 of the Public Health Service Act (42 U.S.C. 247d), the Secretary of HHS hereby **DIRECTS** as follows:

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[1] *See* CDC, *Operational Strategy for K-12 Schools through Phased Mitigation* (https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/operation-strategy.html#vaccination.)

[2] A forthcoming technical amendment to the current COVID-19 Public Readiness and Emergency Preparedness (PREP) Act declaration will clarify that liability immunity extends to persons deemed qualified or authorized to order and administer COVID-19 vaccines, including in such cases where vaccines are authorized, approved or licensed by FDA and recommended by CDC (including those adopted from ACIP recommendations), such as recommendations for the booster doses referenced herein.

As of September 25, 2021, all CDC COVID-19 Vaccination Program enrolled providers shall make immediately available and administer a booster dose of Pfizer-BioNTech COVID-19 vaccine to any and all individuals seeking such a dose who have completed their primary series of Pfizer-BioNTech COVID-19 vaccine at least six months ago and (1) who are 65 years or older; (2) who are 18 years or older and are residents in long term care settings; (3) who are 18 years or older with underlying medical conditions as described in CDC clinical guidance and in accordance with the CDCs recommendation[3]; or (4) who are 18 years or older with increased risk of getting COVID-19 disease due to occupational or institutional exposure, such as frontline essential workers and healthcare workers[4] as described in and in accordance with CDC's recommendation.

All enrolled providers in the CDC COVID-19 Vaccination Program must comply with this Directive as specified in updated CDC COVID-19 vaccination provider requirements posted at: https://www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html. CDC COVID-19 Vaccination Program enrolled providers and state, territorial, local, or tribal authorities are advised not to use or authorize uses of this booster dose beyond what is set forth in this Directive.

This Directive also applies to all awardees and recipients of HHS grant and cooperative agreement funds, including grants to states and U.S. territories that have been awarded to support, implement, and expand COVID-19 vaccination programs nationwide.

This Directive should be read and implemented consistent with other existing direction from HHS and CDC, including the *COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations (Playbook)* guidance document; prior directives from the HHS Secretary and supplements and addenda to vaccine distribution and vaccine prioritization; the CDC Provider Agreement and related guidance; and any workplan, application, jurisdiction vaccination plan, or other submission from an awardee or recipient of CDC grants or cooperative agreements related to COVID-19 vaccine activities. To the extent this Directive directly conflicts with those documents, this Directive shall be read to replace and supersede those documents.

I thank you for your attention to this matter, as well as for your efforts in the COVID-19 response.

/s/
Xavier Becerra
Secretary

[3] https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html
[4] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html

From: Botticella, Angela (HHS/IOS) [Angela.Botticella@hhs.gov]
Sent: 9/24/2021 12:02:18 PM
To: AJP79 (OS/IOS) [AJP79@hhs.gov]; Mccluskie, Sean E (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=213073a2fc3846959b8c5345a0feb82f-HHS-Sean.Mc]; Chang, Jooyeun (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51ad1a981af745698dabfc0520c48366-HHS-Jooyeun]; Barkoff, Alison (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d2b4133a8bb4b9bb75b97256b0e94a8-HHS-Alison.]; Meyers, David (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cc5ffc86eebf47d0960fd7c6f3970896-HHS-David.M]; Walensky, Rochelle P (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df848b046e3947be9b8809afe76917e9-HHS-aux7-cd]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Espinosa, Diana (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f22e3142e1e84006b78a3552aa395ba0-HHS-DEspino]; Fowler, Elizabeth (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c5db6728afc4989b544d71a46c5ab52-HHS-Elizabe]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Pino, Lisa (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bd3d4c1c688d4fbb82464426aa6bde62-HHS-Lisa.Pi]; Tobias, Constance (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4bfa9cf0498949e6a606d9ae2ad763bf-HHS-Constan]; Barry, Daniel J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a27773dc40564218b76dc8ec50ceb0d5-HHS-daniel.]; Grimm, Christi A (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f016a8789314dae984d5e4c5942161e-HHS-Christi]; Allen, McArthur (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93eba8a553994f9aba359633775c5037-HHS-Mcarthu]; Tripathi, Micky (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc278a20a37546f78a45024ee9398496-HHS-Micky.T]; Avery, Kristin E (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=176b8a6fe0314ec2af87b831359f0280-HHS-Kristin]; Figueroa, Marvin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2ced230fd85545a7aeae9f65a31f0389-HHS-Marvin.]; Pace, Loyce S (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=19740fd3c61746bdb2688803291fa692-HHS-Loyce.P]; Haffajee, Rebecca L (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=671291997e284239a36aa1a1a40f32b0-HHS-Rebecca]; Hild, Jeff (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f9043900ba42489eaa807759976cf68e-HHS-Jeff.Hi]; Levine, Rachel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=14635ebee4ab4367aa606702393a1b78-HHS-Rachel.]; Campbell, Cheryl (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1036d4361e0b4aec86fa0d8cd309f42e-HHS-Cheryl.]; Seshasai, Karuna (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10d711a7284b4593bb917a1e90bef9a5-HHS-Karuna.]; Lovenheim, Sarah (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c63c7970a1fe44d18681fd58f0932cbe-HHS-Sarah.L]; Hollie, Leslie W (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=883fb38e89aa49ea97e55345b3045d3a-HHS-Leslie.]; CMS CBL [CBL@cms.hhs.gov]; Reid, Anne M (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff13493051c448c292ad382a2e36597a-HHS-Anne.Re]; Delphin-Rittmon, Miriam (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=461f407996c049258efad3e4e0a31b5f-HHS-Miriam.]; O'Connell, Dawn (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=7871c174f90c49b3952e7639829f176d-HHS-Dawn.Oc]; Cochran, Norris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=996319874d544434b96eef30e8232610-HHS-norris.]; Pryor, Rachel C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7653ea580364698abbee3c47f2319e9-HHS-Rachel.]; Pierce-Wrobel, Clare A (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9b7d6ebb77c46adb6110424bed7d4d4-HHS-Clare.P]; Despres, Sarah (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e5f3d3f26584babb7b48c3cac8bba82-HHS-Sarah.D]; Villanueva, Josie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0cc22ad942f74e258703fe03653e9aef-HHS-Josie.V]; Rainer, Melanie F (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3d4ecbd2bdad45b780880ca101b517b4-HHS-Melanie]; Lopez, Steven (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f53d967d8c1440e3b71425eadbdba3d9-HHS-Steven.]; Friedman, Jennifer (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8b659c3c18334b48ae8d4e52c2c9f953-HHS-Jennife]; Monahan, John (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1a0982b65108402595c3936585d55e72-HHS-John.Mo]; Cha, Stephen S (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38f075dd58f14eb0a5d405cdcf094eb3-HHS-Stephen]; Barstow, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b5834898554f4193ad955378d81ecb4a-HHS-Kevin.B]; Wilkening, Michael R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ba10c134e6e40638f0c9a545b4ac33c-HHS-Michael]

Subject: Talking Points/Press Release: Booster recommendations

Please see the announcement below from CDC of its Pfizer booster recommendations. Additionally, there are some quick initial topline talking points to help you as you may navigate questions. There is a regular COVID press briefing at 12:30pm today where Dr. Walensky will discuss further.

Topline Booster Messages

This is an important step for millions of Americans to get a booster shot.

- People who got Pfizer and are age 65 and older, at high-risk for severe COVID, or work in a high-risk job can go get their booster, starting at least 6 months after their 2nd shot.
  - Just look at your card, and if it's been more than 6 months and you're in one of these categories, you can go get your booster. It's that simple.
- This is the first group of people eligible, and FDA and CDC will continue to evaluate data over the coming weeks and make determinations for additional populations going forward, including people who got Moderna and J&J.

Boosters will help increase people's protection ahead of the fall and winter, as we fight the Delta variant and try to end this pandemic.

- We are focused on staying ahead of the virus by making sure people have the most protection against COVID-19 infection, severe illness and death.

We are following the science.

- FDA and CDC have determined these booster shots can begin, based on the latest data and evidence, after a thorough, independent and transparent process of evaluating safety and effectiveness.

Our plan prepared us to start this booster rollout this week, and we have been working with providers to make sure people can immediately get their shots.

- We always said that boosters would likely start with people who got their vaccines first in the initial rollout – older Americans and people at high-risk – and thanks to our planning, millions of doses are available across the country to begin offering booster shots in pharmacies, through states, and in health care providers' offices.

From: Media@cdc.gov (CDC) <sohco@cdc.gov>
Sent: Thursday, September 23, 2021 11:59 PM
To: Media@cdc.gov (CDC) <sohco@cdc.gov>
Subject: CDC Media Statement on ACIP Booster Recommendations

Media Statement

For Immediate Release
Thursday, September 23, 2021

Contact: CDC Media Relations
(404) 639-3286

CDC Statement on ACIP Booster Recommendations

Today, CDC Director Rochelle P. Walensky, M.D., M.P.H., endorsed the CDC Advisory Committee on Immunization Practices' (ACIP) recommendation for a booster shot of the Pfizer-BioNTech COVID-19 vaccine in certain populations and also recommended a booster dose for those in high risk occupational and institutional settings. The Food and Drug Administration's (FDA) authorization and CDC's guidance for use are important steps forward as we work to stay ahead of the virus and keep Americans safe.

This updated interim guidance from CDC allows for millions of Americans who are at highest risk for COVID-19 to receive a Pfizer-BioNTech COVID-19 booster shot to help increase their protection.

CDC recommends:

- 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.

Many of the people who are now eligible to receive a booster shot received their initial vaccine early in the vaccination program and will benefit from additional protection. With the Delta variant's dominance as the circulating strain and cases of COVID-19 increasing significantly across the United States, a booster shot will help strengthen protection against severe disease in those populations who are at high-risk for exposure to COVID-19 or the complications from severe disease.

CDC will continue to monitor the safety and effectiveness of COVID-19 vaccines to ensure appropriate recommendations to keep all Americans safe. We will also evaluate with similar urgency available data in the coming weeks to swiftly make additional recommendations for other populations or people who got the Moderna or Johnson & Johnson vaccines.

The following is attributable to Dr. Walensky:

As CDC Director, it is my job to recognize where our actions can have the greatest impact. At CDC, we are tasked with analyzing complex, often imperfect data to make concrete recommendations that optimize health. In a pandemic, even with uncertainty, we must take actions that we anticipate will do the greatest good.

I believe we can best serve the nation's public health needs by providing booster doses for the elderly, those in long-term care facilities, people with underlying medical conditions, and for adults at high risk of disease from occupational and institutional exposures to COVID-19. This aligns with the FDA's booster authorization and makes these groups eligible for a booster shot. Today, ACIP only reviewed data for the Pfizer-BioNTech vaccine. We will address, with the same sense of urgency, recommendations for the Moderna and J&J vaccines as soon as those data are available.

While today's action was an initial step related to booster shots, it will not distract from our most important focus of primary vaccination in the United States and around the world. I want to thank ACIP for their thoughtful discussion and scientific deliberation on the current data which informed my recommendation.

###

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

CDC works 24/7 protecting America's health, safety and security. Whether disease start at home or abroad, are curable or preventable, chronic or acute, or from human activity or deliberate attack, CDC responds to America's most pressing health threats. CDC is headquartered in Atlanta and has experts located throughout the United States and the world.

Angela Botticella
Chief of Staff
Office of the Deputy Secretary
U.S. Department of Health and Human Services
Angela.Botticella@hhs.gov
(b) (6) (cell)

From: Rawlings, Kimberly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AE46D13993DC46E190AE70B61E1D4871-KRAWLING]
Sent: 9/22/2021 10:53:21 AM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
CC: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]
Subject: RE: For review: Pfizer booster PR

Hi Stephanie,

JW has cleared the following quote:

"Today's action demonstrates that science and the currently available data continue to guide the FDA's decision-making for COVID-19 vaccines during this pandemic. After considering the totality of the available scientific evidence and the deliberations of our advisory committee of independent, external experts, the FDA amended the EUA for the Pfizer-BioNTech COVID-19 Vaccine to allow for a booster dose in certain populations," said Acting FDA Commissioner Janet Woodcock, M.D. "This pandemic is dynamic and evolving, with new data about waning immunity in the vaccinated and the effects of booster doses becoming available every day. As we learn more about the efficacy of COVID-19 vaccines and the use of boosters, we will continue to react to the rapidly changing science and keep the public informed."

Thanks,

Kimberly A. Rawlings
Senior Advisor *(detail)*
Office of the Commissioner
U.S. Food and Drug Administration
Tel: 301-796-3818; Mobile: (b) (6)
Kimberly.rawlings@fda.hhs.gov

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Wednesday, September 22, 2021 9:36 AM

To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Rawlings, Kimberly <Kimberly.Rawlings@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: For review: Pfizer booster PR

Absolutely, how about these tweaks?

(b) (5)

Stephanie Caccomo
Media Relations Director

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: (b) (6)
stephanie.caccomo@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

I GOT MY COVID-19 VACCINATION

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Wednesday, September 22, 2021 9:27 AM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: For review: Pfizer booster PR

I was thinking maybe my quote should say more about the dynamic nature of the information and how we are getting more data everyday and will update the public as we arrive at more conclusions. jw

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Wednesday, September 22, 2021 8:33 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Rawlings, Kimberly <Kimberly.Rawlings@fda.hhs.gov>; Jefferson, Erica

<Erica.Jefferson@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Capobianco, Abigail <Abigail.Capobianco@fda.hhs.gov>; Hunt, Alison <Alison.Hunt@fda.hhs.gov>
Subject: For review: Pfizer booster PR

Good morning Janet!

For your review is the current version of the Pfizer booster press release—OCC and CBER cleared. We've highlighted what may change re: indications. We appreciate any edits or comments you may have.

Your script for the media call should be cleared later this morning and we will send that along as soon as we can.

Thanks!

Stephanie Caccomo
Media Relations Director

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
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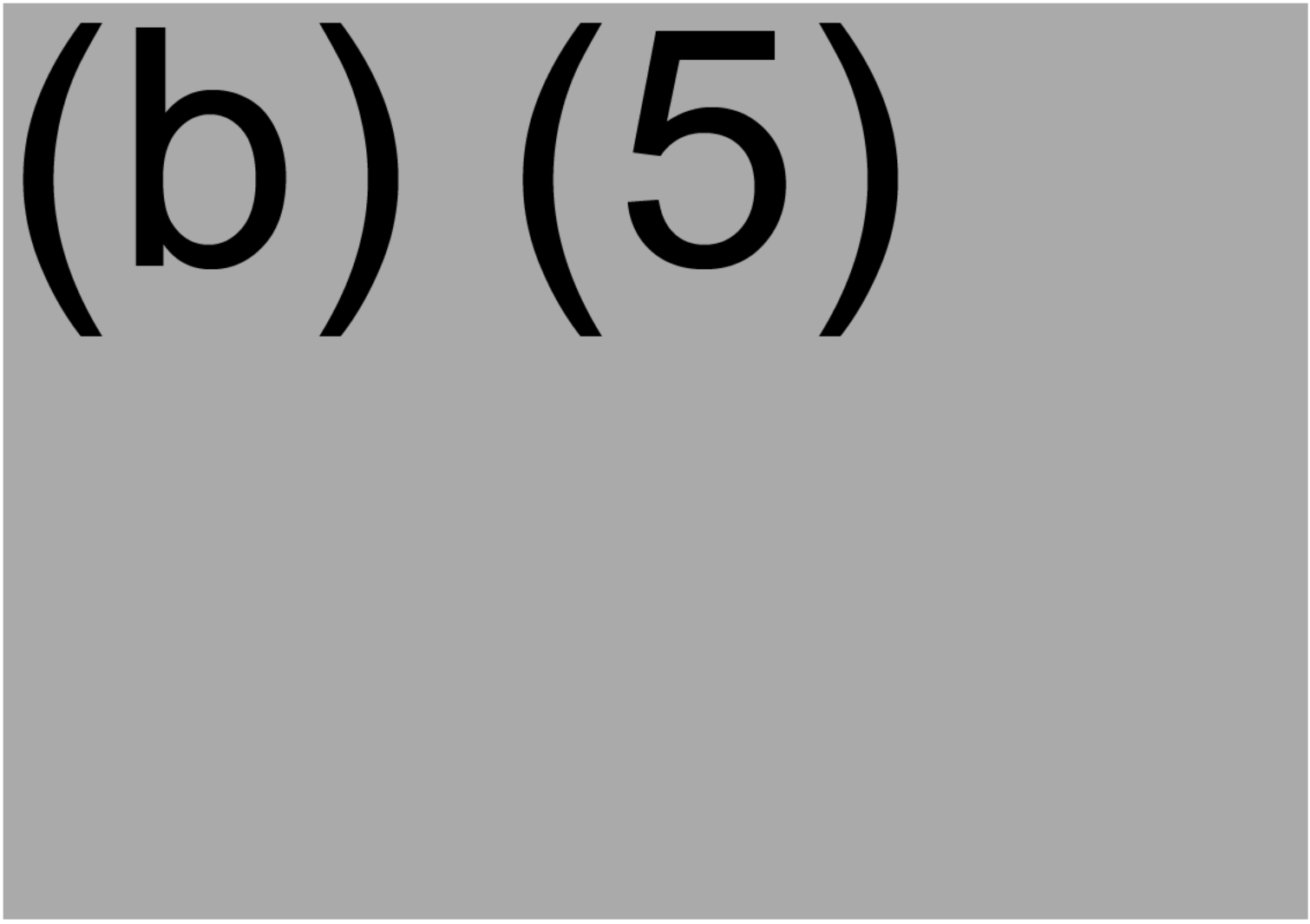
stephanie.caccomo@fda.hhs.gov

From: Tierney, Julia [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1160D300BC4248B790DED292A082E9A8-JULIA.TIERN]
Sent: 10/19/2021 6:22:02 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: Fwd: Booster language.

Just so you have at your fingertips.

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Tuesday, October 19, 2021 6:21:16 PM
To: Berger, Sherri (CDC) <sob8@cdc.gov>
Subject: Booster language.

I don't have the fact sheets yet but here is how we'll be framing (and confirming again 50mcg of Moderna for all booster doses). Note slight change to third bullet for both Pfizer and Moderna to clarify. Close hold of course.



From: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Sent: 9/22/2021 8:33:22 AM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
CC: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Rawlings, Kimberly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae46d13993dc46e190ae70b61e1d4871-KRawling]; Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Capobianco, Abigail [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=660b8e4204f74d4b912265b9c85613bd-Abigail.Cap]; Hunt, Alison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0f683a75ebd4235abf90d887b5f7293-Alison.Hunt]
Subject: For review: Pfizer booster PR
Attachments: Pfizer Booster EUA PR 9.22.2021 815am.docx

Good morning Janet!

For your review is the current version of the Pfizer booster press release—OCC and CBER cleared. We've highlighted what may change re: indications. We appreciate any edits or comments you may have.

Your script for the media call should be cleared later this morning and we will send that along as soon as we can.

Thanks!

Stephanie Caccomo
Media Relations Director

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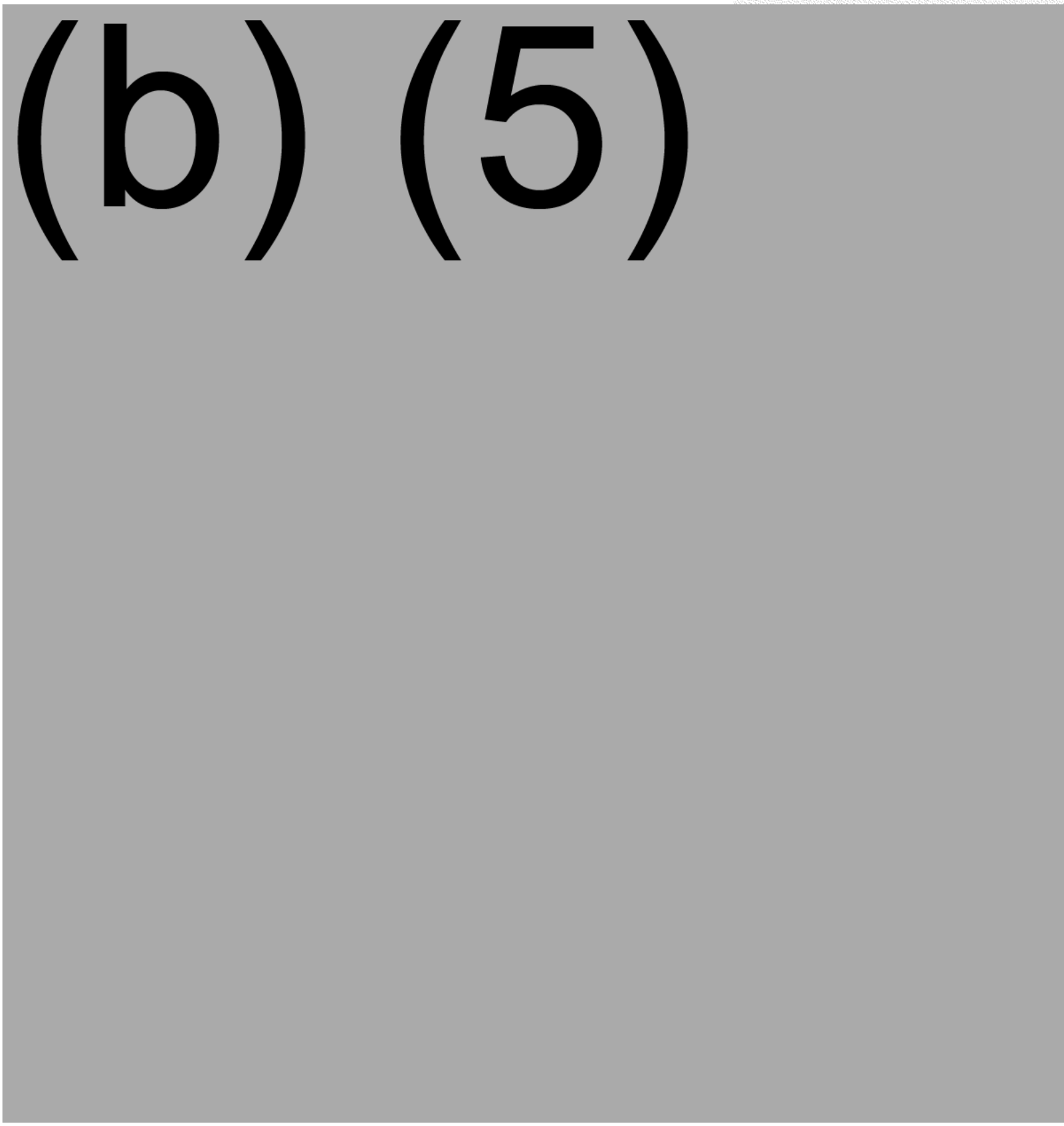
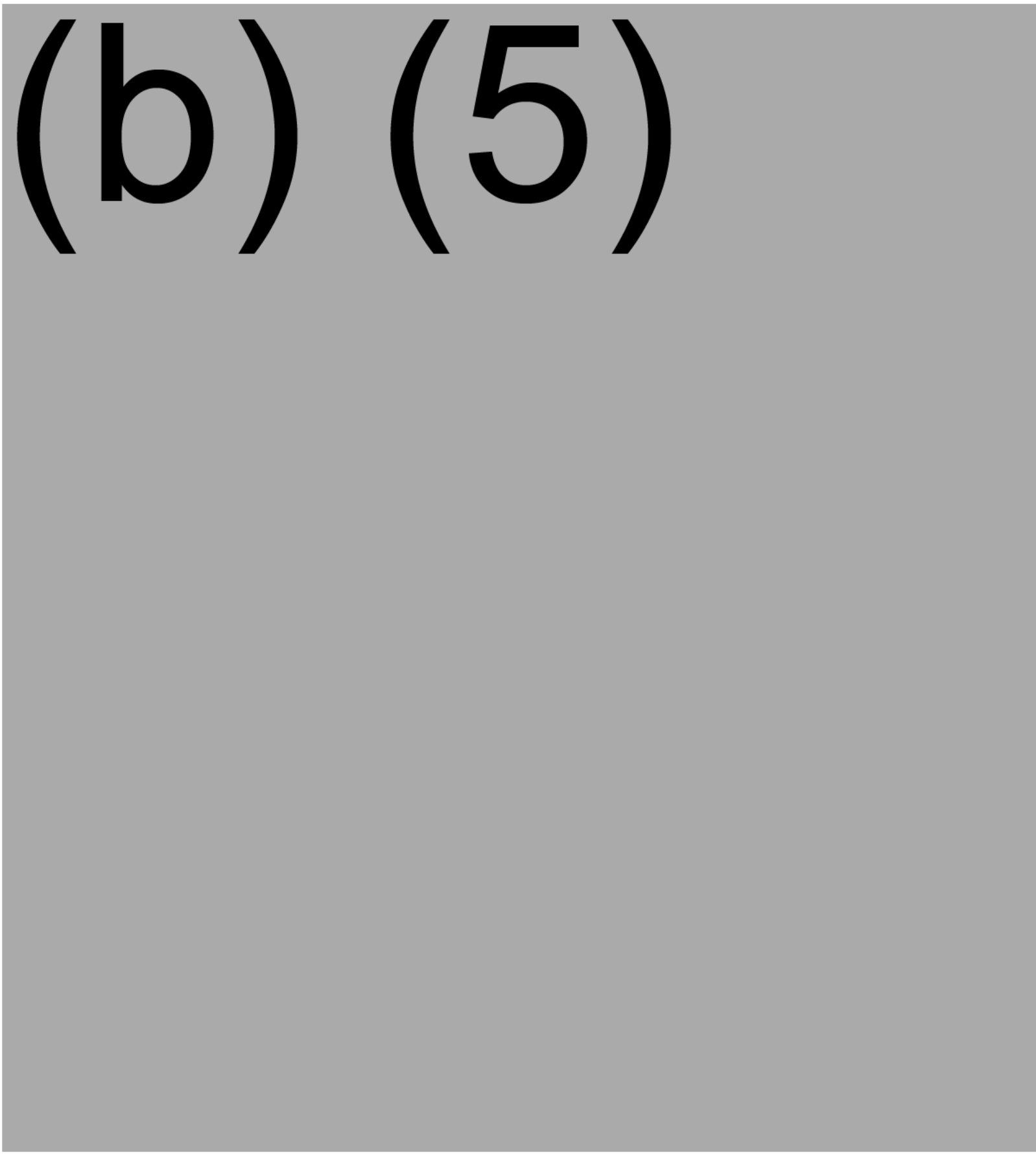
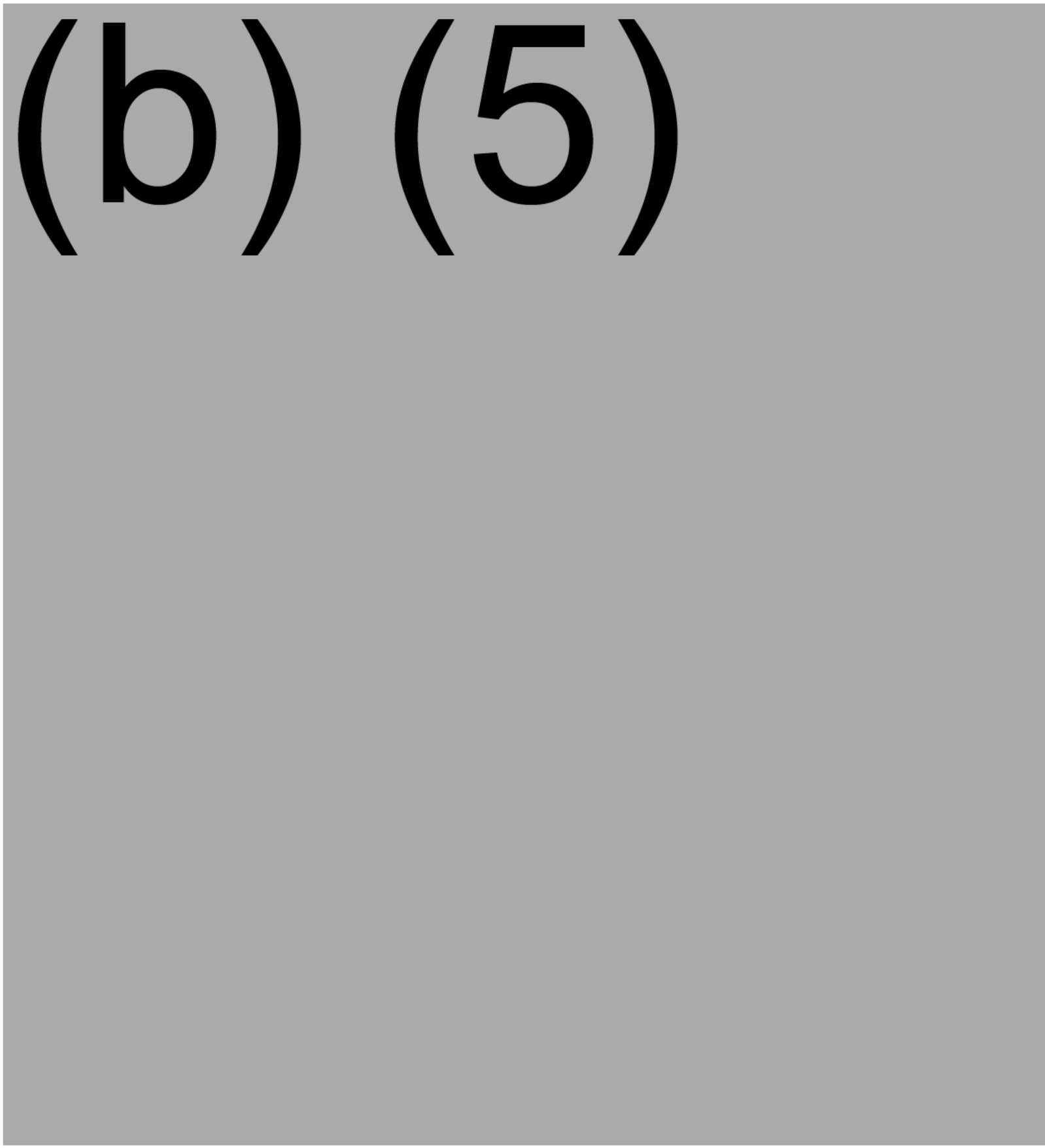

(b) (5)


(b) (5)


(b) (5)

From: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Sent: 9/22/2021 7:22:39 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: RE: Media call script for Pfizer booster
Attachments: Pfizer Booster EUA PR 9.22.2021 FINAL FINAL 712PM.docx

Final press release!

Stephanie Caccomo
Media Relations Director

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Desk: 301.348.1956
Cell: 240.762.8873
stephanie.caccomo@fda.hhs.gov

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Wednesday, September 22, 2021 6:28 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: Media call script for Pfizer booster

No problem, just needed to know it was coming. jw

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Wednesday, September 22, 2021 6:24 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: Media call script for Pfizer booster

We are still resolving final edits from CBER on both script and press release. Will send along as soon

Stephanie Caccomo
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From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Wednesday, September 22, 2021 6:22 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: Media call script for Pfizer booster

Stephanie, are you going to send me a new script with the final conditions of use in it? Also the cleared PR? Thx jw

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Wednesday, September 22, 2021 3:28 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Rawlings, Kimberly <Kimberly.Rawlings@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Capobianco, Abigail <Abigail.Capobianco@fda.hhs.gov>; Hunt, Alison <Alison.Hunt@fda.hhs.gov>
Subject: Media call script for Pfizer booster

Hi Janet-
Attached is the OCC and CBER cleared media call script. We have a few minor technical details to solidify with CBER, but this is mostly final. If you have any comments or edits, please let us know.

Thanks!

Stephanie Caccomo
Media Relations Director

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: (b) (6)
stephanie.caccomo@fda.hhs.gov

INTERNAL DELIBERATIVE DRAFT

PRESS RELEASE

METADATA
Title: FDA Authorizes Booster Dose of Pfizer-BioNTech COVID-19 Vaccine for Certain Populations
Short Title: FDA Authorizes Booster of Pfizer-BioNTech Vaccine for Certain Groups
Detailed Description: FDA amended the emergency use authorization (EUA) for the Pfizer-BioNTech COVID-19 Vaccine to allow for the use of a single booster dose, to be administered at least six months after completion of the primary series with the Pfizer-BioNTech COVID-19 Vaccine in certain populations.
Short Description (formerly called Display Summary): FDA amended the EUA for the Pfizer-BioNTech COVID-19 Vaccine to allow for the use of a single booster dose in certain populations.
Release Date: Sept. 22, 2021
Media Contact Name: FDA Office of Media Affairs
Media Contact Phone: 301-796-4540
Media Contact E-mail: fdaoma@fda.hhs.gov
Contributing Office (center(s) associated with this announcement): CBER
Is this announcement related to health fraud? N

FOR IMMEDIATE RELEASE
Sep. 22, 2021

FDA Authorizes Booster Dose of Pfizer-BioNTech COVID-19 Vaccine for Certain Populations

Today, the U.S. Food and Drug Administration amended the emergency use authorization (EUA) for the Pfizer-BioNTech COVID-19 Vaccine to allow for use of 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.

Today's authorization applies only to the Pfizer-BioNTech COVID-19 Vaccine.

"Today's action demonstrates that science and the currently available data continue to guide the FDA's decision-making for COVID-19 vaccines during this pandemic. After considering the totality of the available scientific evidence and the deliberations of our advisory committee of independent, external experts, the FDA amended the EUA for the Pfizer-BioNTech COVID-19 Vaccine to allow for a booster dose in certain populations such as health care workers, teachers and day care staff, grocery workers and those in homeless shelters or prisons, among others," said Acting FDA Commissioner Janet Woodcock, M.D. "This pandemic is dynamic and evolving, with new data about vaccine safety and effectiveness becoming available every day. As we learn more about the safety and effectiveness of COVID-19 vaccines, including the use of a booster dose, we will continue to evaluate the rapidly changing science and keep the public informed."

The Process for Assessing the Available Data

Comirnaty (COVID-19 Vaccine, mRNA), was approved by the FDA on Aug. 23, for the prevention of COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older. On Aug. 25, 2021, the FDA received a supplement from Pfizer Inc. to their biologics license application for Comirnaty seeking approval of a single booster dose to be administered approximately six months after completion of the primary vaccination series for individuals 16 years of age and older.

As part of the FDA's commitment to transparency, the agency convened a public meeting of its [HYPERLINK "https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-september-17-2021-meeting-announcement"] (VRBPAC) on Sept. 17 to solicit input from independent scientific and public health experts on the data submitted in the application. During the meeting, the vaccine manufacturer presented information and data in support of its application. The FDA also presented its analysis of clinical trial data submitted by the vaccine manufacturer. Additionally, the public was also given an opportunity to provide comment; and FDA invited international and U.S. agencies and external groups, including representatives from the Israeli Ministry of Health, the University of Bristol, U.K. and the Centers for Disease Control and Prevention, to present recent data on the use of vaccine boosters, epidemiology of COVID-19, and real-world evidence on vaccine effectiveness.

The FDA considered the data that the vaccine manufacturer submitted, information presented at the VRBPAC meeting, and the committee's discussion, and has determined that based on the totality of the available scientific evidence, a booster dose of Pfizer-BioNTech COVID-19 Vaccine may be effective in preventing COVID-19 and that the known and potential benefits of a booster dose outweigh the known and potential risks in the populations that the FDA is authorizing for use. The booster dose is authorized for administration to these individuals at least six months following completion of their primary series and may be given at any point after that time.

It's important to note that the FDA-authorized Pfizer-BioNTech COVID-19 Vaccine is the same formulation as the FDA-approved Comirnaty and the vaccines may be used interchangeably.

"We're grateful for the advice of the doctors, scientists, and leading vaccine experts on our advisory committee and the important role they have played in ensuring transparent discussions about COVID-19 vaccines. We appreciate the robust discussion, including the vote regarding individuals over 65 years of age and individuals at high risk for severe disease, as well as the committee's views regarding the use of a booster dose for those with institutional or occupational exposure to SARS-CoV-2," said Peter Marks, M.D., Ph.D., director of FDA's Center for Biologics Evaluation and Research. "The FDA considered the committee's input and conducted its own thorough review of the submitted data to reach today's decision. We will continue to analyze data submitted to the FDA pertaining to the use of booster doses of COVID-19 vaccines and we will make further decisions as appropriate based on the data."

Data Supporting Authorization for Emergency Use

To support the authorization for emergency use of a single booster dose, the FDA analyzed safety and immune response data from a subset of participants from the original clinical trial of the Pfizer-BioNTech COVID-19 Vaccine. In addition, consideration was given to real-world data on the vaccine's efficacy over a sustained period of time provided by both U.S. and international sources, including the CDC, the UK and Israel. The immune responses of approximately 200 participants 18 through 55 years of age who received a single booster dose approximately six months after their second dose were assessed. The antibody response against SARS-CoV-2 virus one month after a booster dose of the vaccine compared to the response one month after the two-dose primary series in the same individuals demonstrated a booster response.

Additional analysis conducted by the manufacturer, as requested by the FDA, compared the rates of COVID-19 accrued during the current Delta variant surge among original clinical trial participants who completed the primary two-dose vaccination series early in the clinical trial to those who completed a two-dose series later in the study. The analysis submitted by the company showed that during the study period of July and August 2021, the incidence of COVID-19 was higher among the participants who completed their primary vaccine series earlier, compared to participants who completed it later. The FDA determined that the rate of breakthrough COVID-19 reported during this time period translates to a modest decrease in the efficacy of the vaccine among those vaccinated earlier.

Safety was evaluated in 306 participants 18 through 55 years of age and 12 participants 65 years of age and older who were followed for an average of over two months. The most commonly reported side effects by the clinical trial participants who received the booster dose of the vaccine were pain, redness and swelling at the injection site, as well as fatigue, headache, muscle or joint pain and chills. Of note, swollen lymph nodes in the underarm were observed more frequently following the booster dose than after the primary two-dose series.

Since Dec. 11, 2020, the Pfizer-BioNTech COVID-19 Vaccine has been available [HYPERLINK "https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use"] for individuals 16 years of age and older. The authorization was expanded on May 20, 2021 to include those 12 through 15 years of age, and again on Aug. 12, 2021 to include the use of a third dose of a three-dose primary series in certain immunocompromised individuals 12 years of age and older. EUAs can be used by the FDA during public health emergencies to provide access to medical products that may be effective in preventing, diagnosing, or treating a disease, provided that the FDA determines that the known and potential benefits of a product, when used to prevent, diagnose, or treat the disease, outweigh the known and potential risks of the product.

The amendment to the EUA to include a single booster dose was granted to Pfizer Inc.

###

Media Contact: [HYPERLINK "mailto:fdaoma@fda.hhs.gov"], 301-796-4540
Consumer Inquiries: [HYPERLINK "mailto:%20ocod@fda.hhs.gov"] or 888-INFO-FDA

From: Berger, Sherri (CDC/OD/OCS)
Sent: Sat, 26 Mar 2022 11:38:49 +0000
To: Walensky, Rochelle (CDC/OD)
Subject: FYI

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Friday, March 25, 2022 4:13 PM
To: Berger, Sherri (CDC/OD/OCS) <sob8@cdc.gov>; O'Connell, Dawn (OS/ASPR/IO) <Dawn.Oconnell@hhs.gov>; Cha, Stephen S (OS) <Stephen.Cha@hhs.gov>; Barclay, Lisa (HHS/OGC) <Lisa.Barclay@hhs.gov>; Pearlman, Aj (OS) <Aj.Pearlman@hhs.gov>; Sams, Ian (HHS/ASPA) <Ian.Sams@hhs.gov>; Jefferson, Erica (FDA/OC) <Erica.Jefferson@fda.hhs.gov>
Subject: RE: [EXTERNAL] FYI -- only for those who got J&J for both the primary and the booster dose

These are the actions planned for next week, as far as I understand (of course not locked in until it's locked in, confidential of course). We're looking at Tuesday. Question below to CDC re timing on the EUI.

- Pfizer EUA [FDA EUA/CDC permissive rec]
  - second booster dose at least 4 months after a first booster dose with any authorized COVID-19 vaccine in individuals 50 years of age and older
  - second booster dose for immunocompromised individuals 12 years and older at least 4 months after the first booster dose with any authorized COVID-19 vaccine

- Moderna EUA [FDA EUA/CDC permissive rec]
  - second booster dose at least 4 months after a first booster dose with any authorized COVID-19 vaccine in individuals 50 years of age and older
  - second booster dose for immunocompromised individuals 18 years and older at least 4 months after the first booster dose with any authorized COVID-19 vaccine

- EUI [CDC] - second booster dose with Moderna or Pfizer for anyone who previously received J&J for both the primary and booster dose at least 4 months [to match EUA] [timing?]

From: Berger, Sherri (CDC/OD/OCS) <sob8@cdc.gov>
Sent: Thursday, March 24, 2022 6:08 PM
To: O'Connell, Dawn (OS) <Dawn.Oconnell@hhs.gov>; Cha, Stephen S (OS) <Stephen.Cha@hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Barclay, Lisa (OS) <Lisa.Barclay@hhs.gov>; Pearlman, Aj (OS) <Aj.Pearlman@hhs.gov>; Sams, Ian C (OS) <Ian.Sams@hhs.gov>
Subject: [EXTERNAL] FYI -- only for those who got J&J for both the primary and the booster dose

Sherri A. Berger, MSPH
Chief of Staff
Centers for Disease Control and Prevention
SBerger@cdc.gov
404.213.8392 cell
404.639.7846 desk

From: Sheehy, Janice
Sent: Tue, 22 Mar 2022 10:06:04 +0000
To: Tierney, Julia (FDA/OC); Berger, Sherri (CDC/OD/OCS)
Subject: RE: Confidential - Consultation on EUA Requests for Additional COVID-19 Vaccine Booster - March 23

Good morning! Thanks, I'll get this invite sent and will add the additional CDC names when I get them.
-j

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Monday, March 21, 2022 9:52 PM
To: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Berger, Sherri (CDC) <sob8@cdc.gov>
Subject: FW: Confidential - Consultation on EUA Requests for Additional COVID-19 Vaccine Booster - March 23

Janice – a few other people from CDC who should join this discussion. Sherri can give you their names. Thanks!

From: Tierney, Julia
Sent: Monday, March 21, 2022 9:51 PM
To: Walensky, Rochelle P (CDC) <aux7@cdc.gov>; Tabak, Lawrence A (NIH) <(b) (6)
O'Connell, Dawn (OS) <Dawn.Oconnell@hhs.gov>; Fauci, Anthony S (NIH) (b) (6)
Levine, Rachel (OS) <Rachel.Levine@hhs.gov>; Murthy, Vivek (OS) <Vivek.Murthy@hhs.gov>; Kessler, David A (OS) <David.Kessler@hhs.gov>; Barclay, Lisa (OS) <Lisa.Barclay@hhs.gov>
Cc: Califf, Robert <(b) (6) @fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Berger, Sherri (CDC) <sob8@cdc.gov>
Subject: Confidential - Consultation on EUA Requests for Additional COVID-19 Vaccine Booster - March 23

As I believe everyone is aware, Pfizer and Moderna have submitted EUA requests for additional booster dose of COVID-19 vaccine for 65 and over and 18 and over, respectively. FDA believes it would be helpful to bring this group together for a consultation on these EUA requests as outlined FDA's EUA authority. This discussion will be separate from the more general discussion of the framework for booster timing and strain selection headed into the Fall, which will be the subject of an upcoming FDA Advisory Committee meeting on April 6 (https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-hold-advisory-committee-meeting-covid-19-vaccines-discuss-future).

Given FDA and CDC schedules, we are proposing to meet on **Wednesday March 23 at 6-7**. We will be in touch with an invitation, but please let me and Janice Sheehy know if Wednesday will absolutely not work for you. We appreciate your flexibility in making yourself available for this important discussion.

Thanks,
Julie

Julia C. Tierney, JD (she/her)
Chief of Staff

U.S. Food and Drug Administration
(301) 796-8602 (office) (forwarded)
(b) (6) (cell)
Julia.Tierney@fda.hhs.gov
Executive Assistant: Susan.Flowers@fda.hhs.gov

From: Berger, Sherri (CDC/OD/OCS)
Sent: Tue, 22 Mar 2022 12:11:12 +0000
To: Gershman, Lynn E. (CDC/OD/OCS)
Cc: Williams, Teresa (CDC/OD/OCS)
Subject: RE: Confidential - Consultation on EUA Requests for Additional COVID-19 Vaccine Booster

yes

From: Gershman, Lynn E. (CDC/OD/OCS) <veu4@cdc.gov>
Sent: Tuesday, March 22, 2022 7:51 AM
To: Berger, Sherri (CDC/OD/OCS) <sob8@cdc.gov>
Cc: Williams, Teresa (CDC/OD/OCS) <coo4@cdc.gov>
Subject: RE: Confidential - Consultation on EUA Requests for Additional COVID-19 Vaccine Booster

Hi Sherri,

Invite below came in for tomorrow evening. Is this one RW should plan to join?

Kindest Regards,

Lynn

Wisdom is knowing the right path to take; Integrity is taking it.

-----Original Appointment-----
From: Califf, Robert <(b) (6) @fda.hhs.gov>
Sent: Tuesday, March 22, 2022 7:36 AM
To: Califf, Robert; Walensky, Rochelle (CDC/OD); Tabak, Lawrence (NIH/OD) [E]; O'Connell, Dawn (OS/ASPR/IO); Fauci, Anthony (NIH/NIAID) [E]; Levine, Rachel (HHS/OASH); Murthy, Vivek (HHS/OASH); Kessler, David (HHS/IOS); Barclay, Lisa (HHS/OGC); Woodcock, Janet (FDA/OC); Marks, Peter (FDA/CBER); Tierney, Julia (FDA/OC); Berger, Sherri (CDC/OD/OCS); Cohn, Amanda (CDC/DDNID/NCBDDD/DBDID); Wharton, Melinda (CDC/DDID/NCIRD/OD)
Subject: Confidential - Consultation on EUA Requests for Additional COVID-19 Vaccine Booster
When: Wednesday, March 23, 2022 6:00 PM-7:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: Please see Zoom below

Hi there,

FDA Commissioner is inviting you to a scheduled ZoomGov meeting.

Join Zoom Meeting

One tap mobile: US: (b)(6)
(b)(6)

Meeting URL:

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Passcode:

(b)(6)

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Dial:

Meeting ID:

Passcode:

(b)(6)

International numbers

Join from an H.323/SIP room system

H.323:

Meeting ID:

Passcode:

(b)(6)

US West)
US East)

SIP:

Passcode:

(b)(6)

From: Sheehy, Janice
Sent: Tue, 22 Mar 2022 11:34:51 +0000
To: Berger, Sherri (CDC/OD/OCS); Tierney, Julia (FDA/OC)
Cc: Cohn, Amanda (CDC/DDNID/NCBDDD/DBDID); Wharton, Melinda (CDC/DDID/NCIRD/OD)
Subject: RE: [EXTERNAL] Confidential - Consultation on EUA Requests for Additional COVID-19 Vaccine Booster - March 23

Will do, thanks, Sherri! -janice

From: Berger, Sherri (CDC/OD/OCS) <sob8@cdc.gov>
Sent: Tuesday, March 22, 2022 7:13 AM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
Cc: Cohn, Amanda C (CDC) <anc0@cdc.gov>; Wharton, Melinda (CDC) <mew2@cdc.gov>
Subject: [EXTERNAL] Confidential - Consultation on EUA Requests for Additional COVID-19 Vaccine Booster - March 23

Please add Amanda & Melinda. Thank you

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Monday, March 21, 2022 9:52 PM
To: Sheehy, Janice (FDA/ORA) <Janice.Sheehy@fda.hhs.gov>; Berger, Sherri (CDC/OD/OCS) <sob8@cdc.gov>
Subject: FW: Confidential - Consultation on EUA Requests for Additional COVID-19 Vaccine Booster - March 23

Janice – a few other people from CDC who should join this discussion. Sherri can give you their names. Thanks!

From: Tierney, Julia
Sent: Monday, March 21, 2022 9:51 PM
To: Walensky, Rochelle P (CDC) <aux7@cdc.gov>; Tabak, Lawrence A (NIH) <(b) (6)>; O'Connell, Dawn (OS) <Dawn.Oconnell@hhs.gov>; Fauci, Anthony S (NIH) <(b) (6)>; Levine, Rachel (OS) <Rachel.Levine@hhs.gov>; Murthy, Vivek (OS) <Vivek.Murthy@hhs.gov>; Kessler, David A (OS) <David.Kessler@hhs.gov>; Barclay, Lisa (OS) <Lisa.Barclay@hhs.gov>
Cc: Califf, Robert <(b) (6)@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Berger, Sherri (CDC) <sob8@cdc.gov>
Subject: Confidential - Consultation on EUA Requests for Additional COVID-19 Vaccine Booster - March 23

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Given FDA and CDC schedules, we are proposing to meet on **Wednesday March 23 at 6-7**. We will be in touch with an invitation, but please let me and Janice Sheehy know if Wednesday will absolutely not work for you. We appreciate your flexibility in making yourself available for this important discussion.

Thanks,
Julie

Julia C. Tierney, JD (she/her)
Chief of Staff

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(b) (6) (cell)
Julia.Tierney@fda.hhs.gov
Executive Assistant: Susan.Flowers@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

I GOT MY COVID-19 VACCINATION

From: Berger, Sherri (CDC/OD/OCS)
Sent: Fri, 25 Mar 2022 11:25:14 +0000
To: Tierney, Julia
Cc: Barclay, Lisa (HHS/OGC)
Subject: RE: [EXTERNAL] FYI -- only for those who got J&J for both the primary and the booster dose

(b)(5)

Highly Sensitive/Recipients Only

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Thursday, March 24, 2022 6:59 PM
To: Berger, Sherri (CDC/OD/OCS) <sob8@cdc.gov>
Cc: Barclay, Lisa (HHS/OGC) <Lisa.Barclay@hhs.gov>
Subject: RE: [EXTERNAL] FYI -- only for those who got J&J for both the primary and the booster dose

I just want to confirm that this should be an EUI (b) (5)

From: Berger, Sherri (CDC/OD/OCS) <sob8@cdc.gov>
Sent: Thursday, March 24, 2022 6:08 PM
To: O'Connell, Dawn (OS) <Dawn.Oconnell@hhs.gov>; Cha, Stephen S (OS) <Stephen.Cha@hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Barclay, Lisa (OS) <Lisa.Barclay@hhs.gov>; Pearlman, Aj (OS) <Aj.Pearlman@hhs.gov>; Sams, Ian C (OS) <Ian.Sams@hhs.gov>
Subject: [EXTERNAL] FYI -- only for those who got J&J for both the primary and the booster dose

Sherri A. Berger, MSPH
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404.213.8392 cell
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