

COVID-19 Vaccines

FDA has rigorous scientific and regulatory processes in place to facilitate development and ensure the safety, effectiveness and quality of COVID-19 vaccines.



Vaccine Status: Currently, there is no FDA-approved or authorized vaccine for the prevention of COVID-19.

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“We are committed to expediting the development of COVID-19 vaccines, but not at the expense of sound science and decision making. We will not jeopardize the public’s trust in our science-based, independent review of these or any vaccines. There’s too much at stake.”

– *Stephen M. Hahn, M.D., FDA Commissioner, and Peter Marks, M.D., Ph.D., Director, Center for Biologics Evaluation and Research*

FDA COVID-19 Vaccine Information

Type of Information



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Date	Update	Type
11/20/2020	<p>Coronavirus (COVID-19) Update: FDA Announces Advisory Committee Meeting to Discuss COVID-19 Vaccine Candidate (/news-events/press-announcements/coronavirus-covid-19-update-fda-announces-advisory-committee-meeting-discuss-covid-19-vaccine)</p> <p>The FDA has scheduled a meeting of its Vaccines and Related Biological Products Advisory Committee (VRBPAC) on Dec. 10 to discuss the request for emergency use authorization (EUA) of a COVID-19 vaccine from Pfizer, Inc. in partnership with BioNTech Manufacturing GmbH.</p>	Press Release / Public Statement
11/20/2020	<p>The FDA published new information about the vaccine development and review process:</p> <ul style="list-style-type: none"> • Vaccine Development 101 (/vaccines-blood-biologics/development-approval-process-cber/vaccine-development-101) • Emergency Use Authorization for Vaccines Explained (/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained) • The Path for a COVID-19 Vaccine from Research to Emergency Use Authorization (PDF-723KB) (/media/143890/download) 	Consumer Information
11/19/2020	<p>FDA and Vaccinate Your Family Talk COVID With Minority Community Leaders (https://youtu.be/mljWfYno3xc) ↗ (http://www.fda.gov/about-fda/website-policies/website-disclaimer)</p> <p>FDA leaders participate in a virtual meeting with racial and ethnic minority community members about FDA's COVID-19 vaccine work.</p>	Event

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FDA Leaders on Vaccines

 #FDAVaccineFacts (<https://twitter.com/SteveFDA/timelines/1307026376571129856>)

Featured Videos

Tell Me More | Episode 1 | Tell Me More Ab...



Learn more about how vaccines are developed from Dr. Anthony Fauci, NIH, Dr. Stephen Hahn, FDA, and other HHS leaders. (6 minutes, 32 seconds)

Coronavirus Vaccine Update From the FDA



Dr. Peter Marks, director of the FDA's Center for Biologics Evaluation and Research (CBER) talks about the FDA vaccine approval process. (39 minutes)

- Dr. Stephen Hahn – Remarks (</news-events/speeches-fda-officials/dr-hahns-remarks-national-consumers-league-vaccine-review-process-09292020>) to the National Consumers League on the vaccine review process (9/29/2020)
- Dr. Stephen Hahn – Opening testimony (</news-events/congressional-testimony/covid-19-update-federal-response-fda-opening-remarks-09232020>) before the U.S. Senate Health, Education, Labor and Pension Committee (9/23/2020)

Podcasts / Audio

FDA Commissioner on the Radio: COVID-19 & FDA

(<https://www.radio.com/kdkaradio/podcasts/the-kdka-radio-morning-show-with-larry-richert-and-kevin-battle-268/fda-commissioner-stephen-hahn-348764807>)  (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>)

FDA Commissioner Stephen Hahn joins a local radio morning show to discuss how FDA facilitates medical countermeasures for COVID-19, including vaccines and therapeutics.

FDA Insight: Vaccines for COVID-19 (/news-events/fda-insight/fda-insight-vaccines-covid-19-part-2)

Dr. Peter Marks, director of the FDA's Center for Biologics Evaluation and Research, discusses vaccines as they relate to COVID-19. Find out more about “herd immunity,” Operation Warp Speed, and vaccine distribution in this episode.

Publications

USA Today: I'm the FDA point person on COVID-19 vaccines. We'll make sure they're safe and effective. (<https://www.usatoday.com/story/opinion/2020/10/27/fda-covid-vaccine-ensuring-safety-and-efficacy-column/6047702002/>) [↗](http://www.fda.gov/about-fda/website-policies/website-disclaimer) (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>) (10/27/2020)

NEJM Perspective: Emergency Use Authorization of Covid Vaccines — Safety and Efficacy Follow-up Considerations (<https://www.nejm.org/doi/full/10.1056/NEJMp2031373>) [↗](http://www.fda.gov/about-fda/website-policies/website-disclaimer) (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>) (10/16/2020)

Health Affairs: Ensuring The Safety And Effectiveness Of A COVID-19 Vaccine (<https://www.healthaffairs.org/doi/10.1377/hblog20200814.996612/full/>) [↗](http://www.fda.gov/about-fda/website-policies/website-disclaimer) (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>) (8/18/2020)

JAMA Viewpoint: Unwavering Regulatory Safeguards for COVID-19 Vaccines (<https://jamanetwork.com/journals/jama/fullarticle/2769421>) [↗](http://www.fda.gov/about-fda/website-policies/website-disclaimer) (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>) (8/7/2020)

Op-Ed: FDA commissioner: No matter what, only a safe, effective vaccine will get our approval (https://www.washingtonpost.com/opinions/fda-commissioner-no-matter-what-only-a-safe-effective-vaccine-will-get-our-approval/2020/08/05/e897d920-d74e-11ea-aff6-220dd3a14741_story.html) [↗](http://www.fda.gov/about-fda/website-policies/website-disclaimer) (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>) (8/5/2020)

Vaccine Events

10/22/2020: Vaccines and Related Biological Products Advisory Committee Meeting (</advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-october-22-2020-meeting-announcement>)

General Vaccine Basics

Vaccines.gov (<https://www.vaccines.gov/basics>)

Answers to common vaccine questions.

Vaccine Development and Availability

- [Vaccine Development 101 \(/vaccines-blood-biologics/development-approval-process-cber/vaccine-development-101\)](/vaccines-blood-biologics/development-approval-process-cber/vaccine-development-101)
 - [Emergency Use Authorization for Vaccines Explained \(/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained\)](/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained)
 - [The Path for a COVID-19 Vaccine from Research to Emergency Use Authorization \(PDF-723KB\) \(/media/143890/download\)](/media/143890/download)
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Vaccines and Related Biological Products Advisory Committee (</advisory-committees/blood-vaccines-and-other-biologics/vaccines-and-related-biological-products-advisory-committee>)

The Committee reviews and evaluates data concerning the safety, effectiveness, and appropriate use of vaccines.

Information for Consumers (</vaccines-blood-biologics/resources-you-biologics/consumers-biologics>)

Information for Vaccine Developers

Go to FDA's Center for Biologics Evaluation and Research (CBER) (</vaccines-blood-biologics/industry-biologics/coronavirus-covid-19-cber-regulated-biologics>) to find information about:

- **Who** to contact if you are developing a CBER-regulated product such as a vaccine
- **What** to include in a vaccine-related submission
- **How** to submit a vaccine-related application

- **Guidance** on conducting clinical trials

Spotlight

Guidance for Industry

Development and Licensure of Vaccines to Prevent COVID-19 (/regulatory-information/search-fda-guidance-documents/development-and-licensure-vaccines-prevent-covid-19)

Emergency Use Authorization for Vaccines to Prevent COVID-19 (/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-vaccines-prevent-covid-19)