

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
189th Meeting of the Vaccines and Related Biological Products
Advisory Committee
May 22, 2025

Topic: The committee will meet in open session to discuss and make recommendations on the selection of the 2025-2026 Formula for COVID-19 vaccines for use in the United States.

EST Time	Presentation/Presenter
8:30 a.m.	<p><u>Opening Remarks: Call to Order and Welcome (10 Min)</u></p> <p>Arnold Monto, M.D. Acting Chair, VRBPAC Professor Emeritus of Public Health and Epidemiology University of Michigan</p> <p>Vinayak Prasad, M.D., M.P.H. Director, Center for Biologics Evaluation and Research</p> <p><u>Administrative Announcements, Roll Call, Introduction of Committee, Conflict of Interest Statement (10 Min)</u></p> <p>CDR Valerie Marshall, Designated Federal Official</p>
8:50 a.m.	<p><u>Introduction (15 Min Total including Q/A)</u></p> <p>Jerry Weir, Ph.D. (10 Min) Director Division of Viral Products (DVP) Office of Vaccines Research and Review (OVRR) CBER, FDA</p> <p>Q/A: 5 Min</p>
9:05 a.m.	<p><u>CDC Presentations (60 Min Total including Q/A)</u></p> <p>Update on Current Epidemiology of COVID-19 and SARS-CoV-2 genomics (25 Min)</p> <p>Natalie J. Thornburg, Ph.D. Chief of the Respiratory Viruses Laboratory Branch Coronavirus and Other Respiratory Viruses Division <i>National Center for Immunization and Respiratory Diseases, CDC</i></p> <p>Q/A: 5 Min</p>

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	<p>Updates on COVID-19 Vaccine Effectiveness (25 Min)</p> <p>Ruth Link-Gelles, Ph.D., M.P.H. CDR, U.S. Public Health Service Coronavirus and Other Respiratory Viruses Division National Center for Immunization and Respiratory Diseases, CDC</p> <p>Q/A: 5 Min</p>
10:05 a.m.	<p><u>TAG-CO-VAC Presentation (35 Min Total including Q/A)</u></p> <p>TAG-CO-VAC May 2025 recommendation on antigen composition of COVID-19 vaccines (25 Min)</p> <p>Kanta Subbarao, M.B.B.S., M.P.H. Professor Department of Microbiology and Immunology Faculty of Medicine Laval University</p> <p>Q/A: 10 Min</p>
10:40 a.m.	<p>Break (20 Min)</p>
11:00 a.m.	<p><u>Moderna Presentation (20 Min Total)</u></p> <p>Moderna COVID-19 Vaccines Update</p> <p>Spyros Chalkias, M.D. Sr. Director, Clinical Development - COVID-19 Vaccines</p> <p>Darin Edwards, Ph.D. Executive Director, COVID-19 Program Lead</p>
11:20 a.m.	<p><u>Pfizer Presentation (20 Min Total)</u></p> <p>Pfizer/BioNTech COVID-19 Vaccines Update</p> <p>Kayvon Modjarrad, M.D., Ph.D. Executive Director, Vaccine Research and Development</p>

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11:40 p.m.	<p><u>Novavax Presentation (20 Min Total)</u></p> <p>Novavax COVID-19 Vaccines Update</p> <p>Robert Walker, M.D. Senior Vice President, Novavax Chief Medical Officer</p> <p>Tonya Colpitts, Ph.D. Associate Vice President, Sanofi Global Project Head – Vaccines, R&D</p>
12:00 p.m.	<p><u>FDA Presentation (20 Min Total)</u></p> <p>FDA Considerations and Recommendation for Changes to COVID-19 Vaccine Formula Composition (20 Min)</p> <p>Jerry Weir, Ph.D. Director, Division of Viral Products Office of Vaccines Research and Review, CBER, FDA</p>
12:20 p.m.	<p><u>Lunch (40 Min)</u></p>
1:00 p.m.	<p><u>Open Public Hearing (60 Min)</u></p>
2:00 p.m.	<p><u>Additional Q & A for CDC, FDA, and Industry Presenters (30 Min)</u></p>
2:30 p.m.	<p><u>Committee Discussion of Vaccine Formula Selection and Voting (up to 120 Min)</u></p>
NLT 4:30 p.m.	<p><u>Meeting Adjourned - DFO</u></p>