

**FOOD AND DRUG ADMINISTRATION (FDA)**  
**Center for Biologics Evaluation and Research (CBER)**  
**189<sup>th</sup> 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.**

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



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

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



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

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