

**FOOD AND DRUG ADMINISTRATION (FDA)**  
**Center for Biologics Evaluation and Research (CBER)**  
**185<sup>th</sup> Meeting of the Vaccines and Related Biological Products**  
**Advisory Committee**  
**June 5, 2024**  
**AGENDA**

**Topic: The committee will meet in open session to discuss and make recommendations on the selection of the 2024-2025 Formula for COVID-19 vaccines.**

<b>EST Time</b>	<b>Presentation/Presenter</b>
<b>8:30 a.m.</b>	<p><b><u>Opening Remarks: Call to Order and Welcome (5 Min)</u></b></p> <p>Arnold Monto, M.D. Acting Chair, VRBPAC            Professor Emeritus of Public Health and Epidemiology            University of Michigan</p> <p><b><u>Administrative Announcements, Roll Call, Introduction of Committee, Conflict of Interest Statement (15 Min)</u></b></p> <p>Kathleen Hayes, M.P.H.            Designated Federal Officer, VRBPAC            Division of Scientific Advisors and Consultants            Center for Biologics Evaluation and Research (CBER), FDA</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 the COVID-19 Pandemic and SARS-CoV-2 Variants (25 Min)</b></p> <p>Natalie J. Thornburg, Ph.D.            Acting Chief, Laboratory Branch            Coronavirus and Other Respiratory Viruses Division            National Center for Immunization and Respiratory Diseases, CDC</p> <p>Q/A – 5 Min</p>

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	<p><b>Update 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 Vaccine Effectiveness Program Lead 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>WHO Presentation</u> (35 Min Total including Q/A)</b></p> <p><b>WHO TAG-CO-VAC May 2024 recommendation on the antigen composition of COVID-19 vaccines (25 Min)</b></p> <p>David Wentworth, Ph.D. Chair World Health Organization Technical Advisory Group on Coronavirus Vaccines</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</u> (20 Min Total)</b></p> <p><b>Moderna COVID-19 Vaccines Update</b></p> <p>Frances Priddy, M.D., M.P.H. Executive Director, Clinical Development - COVID-19 Vaccines</p> <p>Darin Edwards, Ph.D. Executive Director, COVID-19 Program Lead</p>
<b>11:20 a.m.</b>	<p><b><u>Pfizer presentation</u> (20 Min Total)</b></p> <p><b><u>2024-2025 COVID-19 Vaccine Formula: Pfizer/BioNTech Clinical and Preclinical Supportive Data</u></b></p> <ul style="list-style-type: none"> <li>• Epidemiology &amp; Real-World Evidence</li> </ul>

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	<ul style="list-style-type: none"> <li>• XBB.1.5 Omicron-Adapted Vaccine Clinical Humoral Immune Response</li> <li>• Preclinical Evaluation of Contemporary Variant Vaccines</li> </ul> <p>Kayvon Modjarrad, M.D., Ph.D. Executive Director, Viral Vaccines &amp; Immunology</p>
<b>11:40 p.m.</b>	<p><b><u>Novavax presentation</u> (20 Min Total)</b></p> <p><b>Novavax Data in Support of 2024-2025 Vaccine Update</b></p> <p>Robert Walker, M.D. Senior Vice President, Chief Medical Officer</p>
<b>12:00 p.m.</b>	<p><b><u>FDA Presentation</u> (20 Min Total)</b></p> <p><b>FDA Considerations and Recommendation for Changes to COVID-19 Vaccine Formula Composition (20 Min)</b></p> <p>Jerry Weir, Ph.D. Director, Division of Viral Products Office of Vaccines Research and Review, CBER, FDA</p>
<b>12:20 p.m.</b>	<b><u>Lunch</u> (40 Min)</b>
<b>1:00 p.m.</b>	<b><u>Open Public Hearing</u> (60 Min)</b>
<b>2:00 p.m.</b>	<b><u>Additional Q &amp; A for CDC, FDA, and Industry Presenters</u> (20 Min)</b>
<b>2:20 p.m.</b>	<b><u>Break</u> (10 Min)</b>
<b>2:30 p.m.</b>	<b><u>Committee Discussion of Vaccine Formula Selection and Voting</u> (120 Min)</b>
<b>3:26 p.m.</b>	<b><u>Meeting Adjourned - DFO</u></b>