

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
185th 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.

EST Time	Presentation/Presenter
8:30 a.m.	<p><u>Opening Remarks: Call to Order and Welcome (5 Min)</u></p> <p>Arnold Monto, M.D. Acting Chair, VRBPAC Professor Emeritus of Public Health and Epidemiology University of Michigan</p> <p><u>Administrative Announcements, Roll Call, Introduction of Committee, Conflict of Interest Statement (15 Min)</u></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>
8:50 a.m.	<p><u>Introduction (15 Min Total including Q/A)</u></p> <p><u>Jerry Weir, Ph.D. (10 Min)</u> 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><u>Update on Current Epidemiology of the COVID-19 Pandemic and SARS-CoV-2 Variants (25 Min)</u></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>Update on COVID-19 Vaccine Effectiveness (25 Min)</p> <p>Ruth Link-Gelles, Ph.D., M.P.H. 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>
10:05 a.m.	<p><u>WHO Presentation (35 Min Total including Q/A)</u></p> <p>WHO TAG-CO-VAC May 2024 recommendation on the antigen composition of COVID-19 vaccines (25 Min)</p> <p>David Wentworth, Ph.D. Chair World Health Organization Technical Advisory Group on Coronavirus Vaccines</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>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>
11:20 a.m.	<p><u>Pfizer presentation (20 Min Total)</u></p> <p><u>2024-2025 COVID-19 Vaccine Formula: Pfizer/BioNTech Clinical and Preclinical Supportive Data</u></p> <ul style="list-style-type: none">• Epidemiology & Real-World Evidence

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