

**FOOD AND DRUG ADMINISTRATION (FDA)  
Center for Biologics Evaluation and Research (CBER)  
182<sup>nd</sup> Meeting of the Vaccines and Related Biological Products  
Advisory Committee  
June 15, 2023  
AGENDA**

**Topic: The committee will meet in open session to discuss and make recommendations on the selection of strain(s) to be included in the periodic updated COVID-19 vaccines for the 2023-2024 vaccination campaign.**

<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> <ul style="list-style-type: none"> <li>• Arnold Monto, M.D. Acting Chair, VRBPAC Emeritus Professor of Public Health and Epidemiology University of Michigan</li> </ul> <p><b><u>Administrative Announcements, Roll Call, Introduction of Committee, Conflict of Interest Statement (15 Min)</u></b></p> <ul style="list-style-type: none"> <li>• Sussan Paydar, Ph.D. Designated Federal Officer, VRBPAC Division Of Scientific Advisors and Consultants Center for Biologics Evaluation and Research (CBER), FDA</li> </ul>
<b>8:50 a.m.</b>	<p><b><u>FDA Introduction (20 Min)</u></b></p> <p><b>Opening Remarks (5 Min)</b></p> <ul style="list-style-type: none"> <li>• Peter Marks, M.D. Ph.D. Center Director, CBER, FDA</li> </ul> <p><b>Considerations for Selection of the composition of COVID-19 Vaccines for the 2023-2024 Season (10 Min)</b></p> <ul style="list-style-type: none"> <li>• David C. Kaslow, M.D. Director Office of Vaccines Research and Review (OVR), CBER, FDA</li> </ul> <p>Q/A – 5 Min</p>
<b>9:10 a.m.</b>	<p><b><u>CDC Presentations (60 Min total including Q/A)</u></b></p> <p><b>Update on COVID-19 Vaccine Bivalent Effectiveness (25 Min)</b></p> <ul style="list-style-type: none"> <li>• Ruth Link-Gelles, PH.D., M.PH. LCDR, U.S. Public Health Service COVID-19 Vaccine Effectiveness Program Lead National Center for Immunization and Respiratory Diseases, CDC</li> </ul>

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	<p>Q/A – 5 Min</p> <p><b>Update on Current Epidemiology of the COVID-19 Pandemic and SARS-CoV-2 Variants (25 Min)</b></p> <ul style="list-style-type: none"> <li>Natalie J. Thornburg, Ph.D. Acting Chief, Laboratory Branch Coronavirus and Other Respiratory Viruses Division National Center for Immunization and Respiratory Diseases, CDC</li> </ul> <p>Q/A – 5 Min</p>
<b>10:10 a.m.</b>	<p><b><u>WHO Presentation</u> (35 Min Total including Q/A)</b></p> <p><b>WHO TAG-CO-VAC May 2023 recommendation on the antigen composition of COVID-19 vaccines (25 minutes)</b></p> <ul style="list-style-type: none"> <li>Kanta Subbarao, M.D. M.PH. Director, WHO Collaborating Center for Research and Reference on Influenza, The Peter Doherty Institute for Infection and Immunity, Melbourne, Australia</li> </ul> <p>Q/A – 10 Min</p>
<b>10:45 a.m.</b>	<b>Break (15 min)</b>
<b>11:00 a.m.</b>	<p><b><u>Moderna Presentation</u> (30 Min Total including Q/A)</b></p> <p><b>Moderna COVID-19 Variant Vaccines (25 minutes)</b></p> <ul style="list-style-type: none"> <li>Rituparna Das - VP, Clinical Development – Therapeutic Area Head, Respiratory Vaccines</li> <li>Darin Edwards – Executive Director, COVID-19 Lead</li> </ul> <p>Q/A –5 Min</p>

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<b>11:30 a.m.</b>	<p><b><u>Pfizer presentation</u> (30 Min Total including Q/A)</b></p> <p><b>2023-24 COVID-19 Vaccine Formula: Pfizer/BioNTech Clinical and Preclinical Supportive Data (25 minutes)</b></p> <ul style="list-style-type: none"> <li>• Kena A. Swanson, Ph.D. Vice President, Viral Vaccines, Vaccine Research and Development, Pfizer Inc.</li> </ul> <p>Q/A –5 Min</p>
<b>12:00 p.m.</b>	<p><b><u>Novavax presentation</u> (30 Min Total including Q/A)</b></p> <p><b>Novavax Data in Support of 2023-2024 Vaccine Update (25 Min)</b></p> <ul style="list-style-type: none"> <li>• Filip Dubovsky, M.D. Executive Vice President and Novavax Chief Medical Officer Novavax</li> </ul> <p>Q/A – 5 min</p>
<b>12:30 p.m.</b>	<b><u>Lunch</u> (30 Min)</b>
<b>1:00 p.m.</b>	<b><u>Open Public Hearing</u> (60 Min)</b>
<b>2:00 p.m.</b>	<p><b><u>FDA Presentation</u> (30 Min Total including Q/A)</b></p> <p><b>FDA Considerations and Recommendation for Changes to COVID-19 Vaccine Strain Composition (25 Min)</b></p> <ul style="list-style-type: none"> <li>• Jerry Weir, Ph.D. Director, Division of Viral Products Office of Vaccines Research and Review, CBER, FDA</li> </ul> <p>Q/A - 5 Min</p>
<b>2:30 p.m.</b>	<b><u>Additional Q &amp; A for CDC, FDA and Sponsor Presenters</u> (20 Min)</b>
<b>2:50 p.m.</b>	<b><u>Break</u> (10 min)</b>

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<b>3:00 p.m.</b>	<b><u>Committee Discussion of Vaccine Strain Selection and Voting</u></b> <b>(120 Min)</b>
<b>5:00 p.m.</b>	<b><u>Meeting Adjourned - DFO</u></b>