

**FOOD AND DRUG ADMINISTRATION (FDA)**  
**Center for Biologics Evaluation and Research (CBER)**  
**171<sup>st</sup> Meeting of the Vaccines and Related Biological Products**  
**Advisory Committee**  
**April 6, 2022**  
**DRAFT AGENDA**

**Topic: The committee will meet in open session to discuss considerations for COVID-19 vaccine booster doses and the process for COVID-19 vaccine strain selection to address current and emerging variants**

<b>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>Arnold Monto, M.D. Acting Chair, VRBPAC  Emeritus Professor of Public Health and Epidemiology, University of Michigan</p> <p><b><u>Administrative Announcements, Roll Call, Introduction of Committee, Conflict of Interest Statement (20 min)</u></b></p> <p>Prabhakara Atreya, Ph.D. Acting Designated Federal Officer, VRBPAC  Director, Division Scientific Advisors and Consultants, CBER, FDA</p>
<b>9:00 a.m.</b>	<p><b><u>FDA Introduction (15 min)</u></b></p> <p><b>Welcome (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>COVID-19 vaccines: Framework for Future Decisions on Strain Composition and Use of Additional Booster Doses (10 min)</b></p> <ul style="list-style-type: none"> <li>• Doran Fink, M.D., Ph.D.  Deputy Director - Clinical  Division of Vaccines and Related Product Applications (DVRPA)  Office of Vaccines Research and Review (OVRP), CBER, FDA</li> </ul>
<b>9:15 a.m.</b>	<p><b><u>Update on the Epidemiology of SARS-CoV-2 Strains (35 min)</u></b></p> <ul style="list-style-type: none"> <li>• CDR Heather Scobie, Ph.D, M.PH. (30 min)  Deputy Team Lead, Surveillance and Analytics  Epidemiology Task Force  COVID-19 Emergency Response  Centers for Disease Control and Prevention (CDC)</li> <li>• Q/A – 5 min</li> </ul>
<b>9:50 a.m.</b>	<p><b><u>COVID-19 Vaccine Effectiveness in Children and Adults (25 min)</u></b></p> <ul style="list-style-type: none"> <li>• LCDR Ruth Link-Gelles, PhD, M.PH. (20 min)  Program Lead, COVID-19 Vaccine Effectiveness  Epidemiology Task Force</li> </ul>

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	<p>COVID-19 Emergency Response Centers for Disease Control and Prevention (CDC)</p> <ul style="list-style-type: none"> <li>• Q/A – 5 min</li> </ul>
<b>10:20 a.m.</b>	<p><b>Israeli Experience with Fourth Booster Doses in Older Adults (20 min)</b></p> <ul style="list-style-type: none"> <li>• Sharon Alroy-Preis, M.D. M.PH.M.B.A – (10 min) Director, Public Health Services Ministry of Health, Jerusalem, Israel</li> <li>• Ron Milo. Ph.D. - (5 Min) Professor, Dept. of Plant and Environmental Sciences, Dean of Education, Weizmann Institute, Rehovot, Israel</li> </ul> <p>Q/A – 5 min</p>
<b>10:40 a.m.</b>	<b>Break (10 min)</b>
<b>10:50 a.m.</b>	<p><b>Predicting Future SARS-CoV-2 Variants (30 min)</b></p> <p><b>SARS-CoV-2 Antigenic Space</b></p> <ul style="list-style-type: none"> <li>• John Beigel, M.D. (10 min) Associate Director for Clinical Research Division of Microbiology and Infectious Diseases Office of the Director, NIAID, NIH</li> </ul> <p><b>Continuing SARS-CoV-2 evolution under population immune pressure</b></p> <ul style="list-style-type: none"> <li>• Trevor Bedford, Ph.D. (10 Min) Professor, Fred Hutchinson Cancer Research Center Investigator, Howard Hughes Medical Inst. Seattle, WA</li> <li>• Q &amp;A – 10 Min</li> </ul>
<b>11:20 a.m.</b>	<p><b>Modeling of Future U.S. COVID-19 Outbreaks (30 min)</b></p> <ul style="list-style-type: none"> <li>• Christopher Murray, M.D. D.Phil. (20 Min) Professor and Chair Department of Health Metrics Sciences Director, Institute for Health Metrics and Evaluation (IHME) University of Washington, Seattle, WA</li> <li>• Q &amp;A – 10 Min</li> </ul>

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<b>11:50 a.m.</b>	<p><b>WHO Perspective on Variants for COVID-19 Vaccine Composition (20 min)</b>  <b>Technical Advisory Group on COVID-19 Vaccine Composition (TAG-CO-VAC)</b></p> <ul style="list-style-type: none"> <li>• Kanta Subbarao, M.D. M.PH. (15 min)  Director, WHO Collaborating Center for Reference and Research on Influenza, Peter Doherty Institute for Infection and Immunity  Melbourne, Australia</li> <li>• Q &amp;A – 5 min</li> </ul>
<b>12:10 p.m.</b>	<p><b>COVID-19 Vaccine Strain Selection - Points to Consider for Manufacturing Timelines (20 min)</b></p> <ul style="list-style-type: none"> <li>• Robert Johnson, Ph.D. (15 min)  Deputy Assistant Secretary  Director, Medical Countermeasure Programs  Biomedical Advanced Research and Development Authority (BARDA)</li> <li>• Q &amp;A – 5 min</li> </ul>
<b>12:30 p.m.</b>	<p><b>Proposed Framework for Addressing Future COVID-19 Vaccine Strain Composition (30 min)</b></p> <ul style="list-style-type: none"> <li>• Jerry Weir, Ph.D. (20 min)  Director, Division of Viral Products  Office of Vaccines Research and Review (OVRR), CBER, FDA</li> <li>• Q/A – 10 min</li> </ul>
<b>1:00 p.m.</b>	<b><u>Lunch (30 min)</u></b>
<b>1:30 p.m.</b>	<b><u>Open Public Hearing (60 min)</u></b>
<b>2:30 p.m.</b>	<b><u>Committee Discussion of Questions (150 min)</u></b>
<b>5:00 p.m.</b>	<b><u>Meeting Adjourned</u></b>