

**FOOD AND DRUG ADMINISTRATION (FDA)**  
**Center for Biologics Evaluation and Research (CBER)**  
**169<sup>th</sup> Meeting of the Vaccines and Related Biological Products**  
**Advisory Committee**  
**October 14-15, 2021**  
**DRAFT AGENDA**

October 14, 2021: Topic 1: The committee will meet in open session to discuss the EUA of the Moderna COVID-19 mRNA Vaccine for the administration of an booster dose, following completion of the primary series, in individuals 18 years of age and older.

<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>  Arnold Monto, M.D. Acting Chair, VRBPAC  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>  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 (30 min)</u></b></p> <p><b><u>Introduction of the Topic (10 Min)</u></b></p> <ul style="list-style-type: none"> <li>• Peter Marks, M.D. Ph.D. Center Director CBER, FDA</li> </ul> <p><b><u>Background (15 Min)</u></b></p> <ul style="list-style-type: none"> <li>• Sudhakar Agnihothram, Ph.D. Division of Vaccines and Related Product Applications (DVRPA), OVRP, CBER, FDA</li> <li>• Q/A – 5 Min</li> </ul>
<b>9:30 a.m.</b>	<p><b><u>Presentation of Data Relevant to the Need for Boosters (60 Min)</u></b></p> <p>Presentation of Updated Israeli Vaccination Data (40 Min)</p> <ul style="list-style-type: none"> <li>• Speaker 1: Sharon Alroy, M.D., M.P.H, M.B.A., Director of Public Health Services, Ministry of Health Israel</li> <li>• Speaker 2: Ron Milo, Ph.D., Professor, Weitzman Institute, Israel</li> <li>• Q/A - 20 min</li> </ul>
<b>10:30 am</b>	<p><b><u>BREAK (15min)</u></b></p>

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<b>10:45 am</b>	<p><b><u>Sponsor Presentation (45 Min)</u></b></p> <p>Safety and Immunogenicity of a 50 µg Booster Dose of mRNA-1273 (Moderna COVID-19 Vaccine)</p> <ul style="list-style-type: none"> <li>• Jacqueline Miller, MD ID Therapeutic Area Head, Moderna Therapeutics</li> </ul>
<b>11:30 am</b>	<p><b><u>FDA Presentation (45 min)</u></b></p> <ul style="list-style-type: none"> <li>• Tina Mongeau, M.D., M.P.H. Medical Officer Clinical Review Branch 1, DVRPA, OVRP, CBER</li> <li>• Hui-Lee Wong, Ph.D., Associate Director for Innovation Office of Biostatistics and Epidemiology, CBER, FDA</li> <li>• Richard Forshee, Ph.D., Acting Deputy Director Office of Biostatistics and Epidemiology, CBER, FDA</li> <li>• Q/A – 5 min</li> </ul>
<b>12:15 pm</b>	<b><u>Lunch (30 min)</u></b>
<b>12:45 pm</b>	<b><u>Open Public Hearing (60 min)</u></b>
<b>1:45 pm</b>	<b><u>Break (15 Min)</u></b>
<b>2:00 pm</b>	<b><u>Additional Q &amp; A regarding Sponsor and FDA presentations (45 min)</u></b>
<b>2:45 pm</b>	<b><u>Committee Discussion and Voting (120 min)</u></b>
<b>4:45 pm</b>	<b><u>Meeting Adjourned</u></b>