

**FOOD AND DRUG ADMINISTRATION (FDA)  
Center for Biologics Evaluation and Research (CBER)  
163<sup>rd</sup> Meeting of the Vaccines and Related Biological Products  
Advisory Committee  
Silver Spring, MD  
December 17, 2020  
AGENDA**

**Topic:** The Committee will meet in open session to discuss emergency use authorization (EUA) of the Moderna COVID -19 Vaccine for the prevention of COVID-19 in individuals 18 years and older.

Time	Presentation/Presenter
9:00 a.m.	<p><b><u>Opening Remarks: Call to Order and Welcome</u></b> (10 min)</p> <p>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</u></b> (20 min)</p> <p>Prabhakara Atreya, Ph.D. Acting Designated Federal Officer, VRBPAC Director, Division Scientific Advisors and Consultants, CBER, FDA</p>
9:30 a.m.	<p><b><u>FDA Presentation on Emergency Use Authorization</u></b> (15 min)</p> <p>Doran L. Fink, MD, PhD Deputy Director – Clinical Division of Vaccines and Related Products Applications (DVRPA) Office of Vaccines Research and Review (OVRP) Center for Biologics Evaluation and Research (CBER), FDA</p> <p>Q &amp; A: 20 min</p>
10:05 am	<p><b><u>Considerations for placebo-controlled trial design if an unlicensed vaccine becomes available</u></b> (15 min)</p> <p>Steven Goodman, MD, MHS, PhD Associate Dean of Clinical and Translational Research Professor of Epidemiology and Population Health and of Medicine Stanford University School of Medicine</p> <p>Q &amp; A: 25 min</p>

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<b>10:45 am</b>	<p><b><u>Sponsor Presentation: Emergency Use Authorization (EUA) Application for mRNA-1273</u></b> (50 min)</p> <p>Tal Zaks, M.D. Chief Medical Officer and Head of Clinical Development</p> <p>Jacqueline Miller, M.D. FAAP, Senior Vice President, Infectious Diseases Development, Therapeutic Area Head</p> <p>Q &amp; A: 10 min</p>
<b>11:45 a.m.</b>	<b><u>Break</u></b> (15 min)
<b>12:00 p.m.</b>	<b><u>Open Public Hearing</u></b> (60 min)
<b>1:00 p.m.</b>	<b><u>Additional Q &amp; A for Sponsor Presenters</u></b> (30 min)
<b>1:30 p.m.</b>	<b><u>Lunch</u></b> (30 min)
<b>2:00 p.m.</b>	<p><b><u>FDA Presentation and Voting Questions</u></b> (50 min)</p> <p>Rachel Zhang, MD Medical Officer DVRPA, OVRP, CBER, FDA</p> <p>Q &amp; A: 20 min</p>
<b>3:10 p.m.</b>	<b><u>Committee Discussion and Voting</u></b> (125 min)
<b>5:15 p.m.</b>	<b><u>Meeting Adjourned</u></b> - DFO