

**FOOD AND DRUG ADMINISTRATION (FDA)  
Center for Biologics Evaluation and Research (CBER)  
161<sup>st</sup> Meeting of the Vaccines and Related Biological Products Advisory  
Committee  
Silver Spring, MD  
October 22, 2020**

**AGENDA**

**Topic I:** To discuss, in general, the development, authorization and/or licensure of vaccines to prevent COVID-19

**Note:** Committee members are participating via web-conference

<b>Time</b>	<b>Presentation/Presenter</b>
<b>10:00 AM</b>	<p><b><u>Opening Remarks: Call to Order, Introduction of Committee</u></b> <b>Arnold Monto, M.D.</b></p> <p>Temporary Chair, VRBPAC Professor of Epidemiology School of Public Health University of Michigan</p> <p><b><u>Administrative Announcements, Roll Call, Conflict of Interest Statement</u></b></p> <p><b>Prabhakara Atreya, Ph.D.</b> DSAC Director/Designated Federal Officer CBER, FDA</p>
<b>10:20 AM</b>	<p><b><u>FDA Introduction</u></b></p> <p><b>Marion F. Gruber, Ph.D.</b> Director Office of Vaccines Research &amp; Review CBER, FDA</p>
<b>10:35 AM</b>	<p><b><u>Epidemiology, Virology, and Clinical Features of COVID-19</u></b></p> <p><b>Cliff McDonald, M.D.</b> Senior Advisor for Science and Integrity Division of Healthcare Quality Promotion Centers for Disease Control and Prevention</p>
<b>10:55 AM</b>	<p><b><u>NIH activities in the development of vaccines against COVID-19</u></b></p> <p><b>Hilary Marston, M.D., M.P.H.</b> Medical Officer and Policy Advisor for Pandemic Preparedness National Institute of Allergies and Infectious Diseases (NIAID) National Institute of Health (NIH)</p>

<p><b>11:15 AM</b></p>	<p><b><u>BARDA activities in the development of vaccines against COVID-19</u></b></p> <p><b>Robert Johnson, Ph.D.</b>  Director  Influenza and Emerging Infectious Diseases Division  Biomedical Advanced Development Research Authority (BARDA)  Office of the Assistant Secretary for Preparedness and Response (ASPR)  Health and Human Services (HHS)</p>
<p><b>11:35 AM</b></p>	<p><b>Break</b> (10 minutes)</p>
<p><b>11:45 AM</b></p>	<p><b><u>CDC plans for Vaccine Safety monitoring &amp; evaluation during future EUA use and post-licensure</u></b></p> <p><b>Tom Shimabukuro, M.D., M.P.H., M.B.A.</b>  Deputy Director  Immunization Safety Office  Division of Healthcare Quality Promotion  National Center for Emerging and Zoonotic Infectious Diseases  Centers for Disease Control and Prevention</p> <p><b><u>CDC plans for Effectiveness monitoring &amp; evaluation during future EUA use and post-licensure</u></b></p> <p><b>Stephanie Schrag, D.Phil.</b>  Epidemiology Team Lead  Respiratory Diseases Branch/Division of Bacterial Diseases  Centers for Disease Control and Prevention</p>
<p><b>12:05 PM</b></p>	<p><b><u>CBER Surveillance Systems/Postmarketing</u></b></p> <p><b>Steven Anderson, Ph.D.</b>  Director  Office of Biostatistics and Epidemiology  CBER/FDA</p>
<p><b>12:25 PM</b></p>	<p><b><u>Operational aspects of COVID-19 vaccine distribution and tracking</u></b></p> <p><b>CAPT Janell Routh, M.D., M.H.S.</b>  Medical Officer and Program Lead  Division of Viral Diseases  National Center for Influenza and National Respiratory Diseases  Centers for Disease Control and Prevention</p>
<p><b>12:45 PM</b></p>	<p><b>Lunch Break</b> (30 min)</p>
<p><b>1:15 PM</b></p>	<p><b><u>COVID-19 Vaccine Confidence</u></b></p> <p><b>Susan Winckler, R.Ph., Esq.</b>  CEO  Reagan-Udall Foundation (RUF)</p> <p><b>Chris Wilks, Ph.D.</b>  Researcher  RUF</p>

<p><b>1:30 PM</b></p>	<p><b><u>Licensure and Emergency Use Authorization of Vaccines to Prevent COVID-19: Chemistry, Manufacturing, and Controls (CMC) Considerations</u></b></p> <p><b>Jerry Weir, Ph.D.</b>  Director  Division of Viral Products (DVP)  Office of Vaccines Research and Review (OVRR)  CBER, FDA</p>
<p><b>1:55 PM</b></p>	<p><b><u>Licensure and Emergency Use Authorization of Vaccines to Prevent COVID-19: Clinical Considerations</u></b></p> <p><b>Doran Fink, M.D., Ph.D.</b>  Deputy Director  Division of Vaccines and Related Products Applications  Office of Vaccines Research and Review (OVRR)  CBER, FDA</p>
<p><b>2:35 PM</b></p>	<p><b>Break</b> (10 Minutes)</p>
<p><b>2:45 PM</b></p>	<p><b>Open Public Hearing</b> (90 minutes)</p>
<p><b>4:15 PM</b></p>	<p><b>Committee Discussion and Recommendations</b></p>
<p><b>6:30 PM</b></p>	<p><b>Adjourn Meeting</b></p>