FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
161st 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

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

11:15 AM	**COVID-19 Vaccine Development Portfolio** **Robert Johnson, Ph.D.** 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)
11:35 AM	**Break** (10 minutes)
11:45 AM	**CDC plans for Vaccine Safety monitoring & evaluation during future EUA use and post-licensure** **Tom Shimabukuro, M.D., M.P.H., M.B.A.** Deputy Director Immunization Safety Office Division of Healthcare Quality Promotion National Center for Emerging and Zoonotic Infectious Diseases Centers for Disease Control and Prevention **CDC plans for Effectiveness monitoring & evaluation during future EUA use and post-licensure** **Stephanie Schrag, D.Phil.** Epidemiology Team Lead Respiratory Diseases Branch/Division of Bacterial Diseases Centers for Disease Control and Prevention
12:05 PM	**CBER plans for Monitoring COVID-19 Vaccine Safety and Effectivness** **Steven Anderson, Ph.D.** Director Office of Biostatistics and Epidemiology CBER/FDA
12:25 PM	**COVID-19 Vaccine Implementation: Operational aspects of COVID-19 vaccine distribution and tracking** **CAPT Janell Routh, M.D., M.H.S.** Medical Officer and Program Lead Division of Viral Diseases National Center for Influenza and National Respiratory Diseases Centers for Disease Control and Prevention
12:45 PM	**Lunch Break** (30 min)
1:15 PM	**COVID-19 Vaccine Confidence** **Susan Winckler, R.Ph., Esq.** CEO Reagan-Udall Foundation (RUF) **Chris Wilks, Ph.D.** Researcher RUF

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