FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
164th Meeting of the Vaccines and Related Biological Products Advisory Committee
February 26, 2021
AGENDA

Topic: The committee will meet in open session to discuss Emergency Use Authorization (EUA) of the Janssen Biotech Inc. COVID-19 Vaccine for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years and older.

Time	Presentation/Presenter
9:00 a.m.	**Opening Remarks: Call to Order and Welcome** (10 min) Arnold Monto, M.D. Acting Chair, VRBPAC Professor of Public Health and Epidemiology, University of Michigan **Administrative Announcements, Roll Call, Introduction of Committee, Conflict of Interest Statement** (20 min) Prabhakara Atreya, Ph.D. Acting Designated Federal Officer, VRBPAC Director, Division Scientific Advisors and Consultants, CBER, FDA
9:30 a.m.	**Emergency Use Authorization: Overview and Considerations for COVID 19 Vaccines** Maria Allende, MD Branch Chief, Clinical Review Branch 1 Division of Vaccines and Related Products Applications (DVRPA) Office of Vaccines Research and Review (OVRR) Center for Biologics Evaluation and Research (CBER), FDA Presentation – 15 Min Q/A – 5 Min
9:50 a.m.	**Epidemiology of SARS-COV-2 Variants** Adam MacNeil, Ph.D., M.P.H. Deputy Branch Chief for Epidemiology, Respiratory Viruses Branch Division of Viral Diseases, National Center for Immunization and Respiratory Diseases Centers for Disease Control and Prevention (CDC) Presentation - 30 min Q/A - 10 min
10:30 a.m.	**COVID-19 Vaccine Safety Update** Tom Shimabukuro, M.D., M.P.H., M.B.A. (10 minutes) 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)

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	Steven Anderson, PhD, MPP (10 minutes) Director Office of Biostatistics and Epidemiology Center for Biologics Evaluation and Research (CBER), FDA Q/A – 10 Min
11:00 a.m.	**BREAK**
11:10 a.m.	**Sponsor Presentation: Emergency Use Authorization Application for Ad26.COV2.S** Janssen - 60 minutes Johan Van Hoof, M.D. Hanneke Schuitemaker, Ph.D. Macaya Douoguih, M.D., M.P.H. Gregory A. Poland, M.D., F.R.C.P.
12:10 p.m.	**Additional Q & A for Sponsor Presenters** (30 min)
12:40 p.m.	**Lunch** (30 mins)
1:10 p.m.	**Open Public Hearing** (60 mins)
2:10 p.m.	**FDA Review of Efficacy and Safety of the Janssen COVID-19 Vaccine Emergency Use Authorization Request** (50 min) Rachel Zhang, M.D. Yosefa Hefter, M.D. Medical Officers Division of Vaccines and Related Products Applications (DVRPA) Office of Vaccines Research and Review (OVRR) Center for Biologics Evaluation and Research (CBER), FDA
3:00 p.m.	**Break** (10 min)
3:10 p.m.	**Committee Discussion and Voting** (140 min)
5:30 p.m.	**Meeting Adjourned - DFO**