FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
170th Meeting of the Vaccines and Related Biological Products Advisory Committee
October 14-15, 2021
DRAFT AGENDA

October 15, 2021:Topic II: The committee will meet in open session to discuss the EUA of the Janssen Biotech Inc. COVID-19 vaccine for the administration of a booster dose, to individuals 18 years of age and older

Time	Presentation/Presenter
8:30 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
9:00 a.m.	**FDA Introduction (15 min)** **Introduction of the Topic** (5 Min) • Peter Marks, M.D. Ph.D. Center Director CBER, FDA **Janssen COVID-19 Vaccine Application for Emergency Use Authorization of a booster dose** (5 Min) • Sudhakar Agnihothram, Ph.D. Division of Vaccines and Related Product Applications (DVRPA), OVRR, CBER, FDA • Q/A – 5 Min
9:15 am	**Sponsor Presentation (45 Min)** Emergency Use Authorization (EUA) Amendment for a Booster Dose for the Janssen COVID-19 Vaccine (Ad26.COV2.S) • Penny Heaton, M.D. Global Therapeutic Area Head, Vaccines, Janssen Research & Development, Johnson & Johnson • Johan Van Hoof, M.D., Managing Director, Janssen Vaccines & Prevention B.V., Johnson & Johnson • Dan Barouch, M.D., Ph.D. William Bosworth Castle Professor of Medicine Harvard Medical School; Ragon Institute of MGH, MIT, and Harvard;

	Director, Center for Virology and Vaccine Research, Beth Israel Deaconess Medical Center • Sebastian Schneeweiss, M.D., Sc.D., Co-founder and Science Lead, Aetion Inc. • Macaya Douoguih, M.D., M.P.H. Head, Janssen Clinical Development and Medical Affairs, Janssen Vaccines & Prevention B.V., Johnson & Johnson
10:00 am	**FDA Presentation (50 min)** **FDA Review of Effectiveness and Safety of Janssen COVID-19 Vaccine (Ad26.COV2.S) Booster Dose Emergency Use Authorization Amendment** • Rachel Zhang, M.D. & Timothy Brennan, Ph.D., M.D., M.S. 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 **Review of RWE to Assess the Effectiveness of a single dose of Janssen COVID-19 Vaccine (Ad26.COV2.S)** • Artur Belov, Ph.D. Operations Research Analyst Immediate Office of the Director (IOD) Office of Biostatistics and Epidemiology (OBE), CBER, FDA **Review of Post Authorization Safety Data for Janssen COVID-19 Vaccine** • Narayan Nair, M.D. Director Division of Epidemiology Office of Biostatistics and Epidemiology (OBE), CBER, FDA • Q/A – 5 min
10:50 am	**BREAK (10 min)**
11:00 am	**OPEN PUBLIC HEARING (60 min)**

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11:30 am	**Additional Q & A regarding Sponsor and FDA presentations (45 Min)**
12:15 pm	**Lunch (30 Min)**
12:45 pm	**Committee Discussion and Voting (120 min)**
1:30 pm	**Break (15 Min)**
1:45 pm	**DMID 21-0012 – Heterologous Platform Boost Study Mix and Match (45 min)** • Kirsten Lyke, M.D. Professor of Medicine University of Maryland • Q/A – 10 min
2:15 pm	**Committee Discussion of FDA Questions (45 min)**
3:30 pm	**Meeting Adjourned**