FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
169th Meeting of the Vaccines and Related Biological Products Advisory Committee
October 14-15, 2021
DRAFT AGENDA

October 14, 2021:Topic 1: The committee will meet in open session to discuss the EUA of the Moderna COVID-19 mRNA Vaccine for the administration of an booster dose, following completion of the primary series, in 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 (30 min)** **Welcome Remarks** (10 Min) • Peter Marks, M.D. Ph.D. Center Director CBER, FDA **Moderna COVID-19 Vaccine Application for Emergency Use Authorization of a booster dose** (15 Min) • Sudhakar Agnihothram, Ph.D. Division of Vaccines and Related Product Applications (DVRPA), OVRR, CBER, FDA • Q/A – 5 Min
9:30 a.m.	**Booster protection across ages – data from Israel (60 Min)** Presentation of Updated Israeli Vaccination Data (40 Min) • Speaker 1: Sharon Alroy, M.D., M.P.H, M.B.A., Director of Public Health Services, Ministry of Health Israel • Speaker 2: Ron Milo, Ph.D., Professor, Weitzman Institute, Israel • Q/A - 20 min
10:30 am	**BREAK (15min)**

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10:45 am	**Sponsor Presentation (45 Min)** Safety and Immunogenicity of a 50 µg Booster Dose of mRNA-1273 (Moderna COVID-19 Vaccine) • Jacqueline Miller, MD ID Therapeutic Area Head, Moderna Therapeutics
11:30 am	**FDA Review of Effectiveness and Safety of Moderna COVID-19 Vaccine (mRNA-1273) Booster Dose Emergency Use Authorization (45 min)** • Tina Mongeau, M.D., M.P.H. Medical Officer Clinical Review Branch 1, DVRPA, OVRR, CBER **Surveillance Updates of Mycarditis/Pericarditis and mRNA COVID-19 Vaccination in the FDA BEST System** • Hui-Lee Wong, Ph.D., Associate Director for Innovation Office of Biostatistics and Epidemiology, CBER, FDA • Q/A – 5 min
12:15 pm	**Lunch (30 min)**
12:45 pm	**Open Public Hearing (60 min)**
1:45 pm	**Break (15 Min)**
2:00 pm	**Additional Q & A regarding Sponsor and FDA presentations (45 min)**
2:45 pm	**Committee Discussion and Voting (120 min)**
4:30 pm	**Meeting Adjourned**