FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
163rd Meeting of the Vaccines and Related Biological Products Advisory Committee
Silver Spring, MD
December 17, 2020
AGENDA

Topic: The Committee will meet in open session to discuss emergency use authorization (EUA) of the Moderna COVID -19 Vaccine for the prevention of COVID-19 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** (15 min) Doran L. Fink, MD, PhD Deputy Director – Clinical Division of Vaccines and Related Products Applications (DVRPA) Office of Vaccines Research and Review (OVRR) Center for Biologics Evaluation and Research (CBER), FDA Q & A: 20 min
10:05 am	**Considerations for placebo-controlled trial design if an unlicensed vaccine becomes available** (15 min) Steven Goodman, MD, MHS, PhD Associate Dean of Clinical and Translational Research Professor of Epidemiology and Population Health and of Medicine Stanford University School of Medicine Q & A: 25 min

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10:45 am	**Sponsor Presentation: Emergency Use Authorization (EUA) Application for mRNA-1273** (50 min) Tal Zaks, M.D. Chief Medical Officer and Head of Clinical Development Jacqueline Miller, M.D. FAAP, Senior Vice President, Infectious Diseases Development, Therapeutic Area Head Q & A: 10 min
11:45 a.m.	**Break** (15 min)
12:00 p.m.	**Open Public Hearing** (60 min)
1:00 p.m.	**Additional Q & A for Sponsor Presenters** (30 min)
1:30 p.m.	**Lunch** (30 min)
2:00 p.m.	**FDA Review of Efficacy and Safety of Moderna COVID-19 Vaccine Emergency Use Authorization Request** (50 min) Rachel Zhang, MD Medical Officer DVRPA, OVRR, CBER, FDA Q & A: 20 min
3:10 p.m.	**Committee Discussion and Voting** (125 min)
5:00 p.m.	**Meeting Adjourned** - DFO