FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
162nd Meeting of the Vaccines and Related Biological Products Advisory Committee
Silver Spring, MD
December 10, 2020
AGENDA

Topic: The Committee will meet in open session to discuss EUA of the Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 in individuals 16 years of age and older.

Time	Presentation/Presenter
9:00 a.m.	**Opening Remarks: Call to Order and Welcome** Arnold Monto, M.D. Chair, VRBPAC **Administrative Announcements, Roll call, Introduction of Committee, Conflict of Interest Statement** Prabhakara Atreya, Ph.D. Acting Designated Federal Officer, VRBPAC CBER, FDA
9:30 a.m.	**Emergency Use Authorization Overview and Considerations for COVID-19 Vaccines** (30 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
10:00 a.m.	**Epidemiology of COVID-19 in the United States** (10 min) Aron J. Hall, DVM, MSPH, Dipl. ACVPM Co-Lead, Epidemiology Task Force, COVID-19 Response Chief, Respiratory Viruses Branch, Division of Viral Diseases National Center for Immunization and Respiratory Diseases Centers for Disease Control and Prevention Q & A: 5 min
10:15 a.m.	Break
10:30 a.m.	**COVID-19 vaccine post-authorization safety and effectiveness monitoring** (15 min) Nancy Messonnier, MD Director, National Center for Immunization and Respiratory Diseases (NCIRD), Senior Official, Vaccine Task Force CDC

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
162nd Meeting of the Vaccines and Related Biological Products Advisory Committee
Silver Spring, MD
December 10, 2020
AGENDA

	Distribution Overview Anita Patel, PharmD, MS Deputy, Vaccine Task Force CDC Q & A: 5 min
10:50 a.m.	**Considerations for placebo-controlled trial design if an unlicensed vaccine becomes available** (20 min) Steven Goodman, MD, MHS, PhD Associate Dean of Clinical and Translational Research and Professor of Epidemiology and Population Health and of Medicine Stanford University School of Medicine Q & A: 5 min
11:15 a.m.	Lunch - 45 min
12:00 p.m.	**Open Public Hearing** (60 min)
1:00 p.m.	**Sponsor Presentation** (50 min) Moderator: Kathrin U. Jansen, PhD Senior Vice President and Head, Vaccine Research and Development, Pfizer Inc. Presenter: William C. Gruber, MD Senior Vice President, Vaccine Clinical Research and Development, Pfizer Inc. Q & A: 10 min
2:00 p.m.	**FDA Review of Efficacy and Safety of Pfizer-BioNTech COVID-19 Vaccine Emergency Use Authorization Request** (50 min) Susan Wollersheim, MD Medical Officer DVRPA, OVRR, CBER, FDA Q & A: 10 min
3:00 p.m.	Break – 10 min

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
162nd Meeting of the Vaccines and Related Biological Products Advisory Committee
Silver Spring, MD
December 10, 2020
AGENDA

3:10 p.m.	Committee Discussion and Voting (125 min)
5:35 p.m.	Meeting Adjourned