FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
170th Meeting of the Vaccines and Related Biological Products Advisory Committee
October 26, 2021
DRAFT AGENDA

Topic: The committee will meet in open session to discuss Pfizer-BioNTech's Emergency Use Authorization request for administration of their COVID-19 mRNA vaccine to children 5 to 11 years of age.

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 including Q &A))** **Welcome (5 Min)** • Peter Marks, M.D. Ph.D. Center Director, CBER, FDA **Introduction of the Topic (10 Min)** • Doran Fink, M.D., Ph.D. Deputy Director- Clinical Division of Vaccines and Related Product Applications (DVRPA) Office of Vaccines Research and Review (OVRR) CBER, FDA **Background (10 Min)** • Ramachandra Naik, Ph.D Review Committee Chair Division of Vaccines and Related Product Applications (DVRPA) Office of Vaccines Research and Review (OVRR) CBER, FDA • Q/A – 5 Min
9:30 a.m.	**CDC Presentations TBD (60 Min including Q &A)** **Epidemiology of COVID-19 in Children (20 Min)** • Fiona Havers, M.D. Medical Officer, Division of Viral Diseases

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	National Center for Immunization and Respiratory Diseases (NCIRD) Centers for Disease Control and Prevention (CDC) • Q/A - 10 min **Known safety signals (Myocarditis in adolescents and young adults) (20 Min)** • Mathew Oster, M.D. M.PH. Centers for Disease Control and Prevention CDC COVID-19 Response CDC Center on Birth Defects and Developmental Disabilities Pediatric Cardiologist, Sibley Heart Center, Children's Healthcare of Atlanta Emory University School of Medicine and Rollins School of Public Health • Q/A - 10 min
10:30 a.m.	**BREAK (15 min)**
10:45 a.m.	**Sponsor Presentation (50 Min including Q&A)** BNT162b2 (Pfizer-BioNTech COVID-19 Vaccine) – Request for Emergency Use Authorization for Individuals 5 to < 12 Years of Age • William Gruber, M.D.FAAP, FIDSA, FPIDS Senior Vice President, Vaccine Clinical Res. And Development Pfizer Inc. • Q &A – 5 Min
11:35 a.m.	**FDA Presentations (50 min including Q&A)** • FDA review of Pfizer-BioNTech Submission (20 min) Leslie Ball, M.D. Medical Officer, Clinical Review Branch 1, Division of Vaccines and Related Product Applications (DVRPA) Office of Vaccines Research and Review (OVRR), CBER, FDA • Post-Authorization Evaluation (5 min) Hui-Lee Wong, Ph.D. Associate Director for Innovation and Development Office of Biostatistics and Epidemiology (OBE), CBER, FDA • Benefit-Risk Analysis (20 min) Hong Yang, Ph.D. Senior Advisor for Benefit-Risk Assessment

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	Office of Biostatistics and Epidemiology (OBE), CBER, FDA • Q/A – 5 min
12:25 p.m.	**Lunch (35 min)**
1:00 p.m.	**Open Public Hearing (60 min)**
2:00 p.m.	**Break (10 Min)**
2:10 p.m.	**Additional Q & A regarding Sponsor and FDA presentations (45 min)**
2:55 p.m.	**Committee Discussion and Voting (125 min)**
5:00 p.m.	**Meeting Adjourned**