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
FINAL 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 **Pfizer-BioNTech COVID-19 Vaccine:** **Request for Emergency Use Authorization (EUA) Amendment,** **Use of a 2-Dose Primary Series in Children 5-11 Years of Age** **(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 **Pfizer-BioNTech COVID-19 Vaccine** **Emergency Use Authorization Amendment Request** **for Use in Children 5 through 11 Years of Age (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

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
FINAL AGENDA

9:30 a.m.	**CDC Presentations TBD (60 Min including Q &A)** **Epidemiology of COVID-19 in Children Aged 5-11 Years (20 Min)** • Fiona Havers, M.D. Medical Officer, Division of Viral Diseases National Center for Immunization and Respiratory Diseases (NCIRD) Centers for Disease Control and Prevention (CDC) • Q/A - 10 min **mRNA COVID-29 Vaccine-Associated Myocarditis (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 Effectiveness and Safety of Pfizer-BioNTech COVID-19 Vaccine in Children 5 through 11 Years of Age Emergency Use Authorization Amendment (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-Market Active Surveillance of COVID-19 Vaccines in the Pediatric Population in the FDA BEST System (5 min) Hui-Lee Wong, Ph.D. Associate Director for Innovation and Development Office of Biostatistics and Epidemiology (OBE), CBER, FDA • **Benefits-Risks of Pfizer-BioNTech COVID-19 Vaccine for Ages 5 to 11 Years** (20 min) Hong Yang, Ph.D. Senior Advisor for Benefit-Risk Assessment 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)**
4:35 p.m.	**Meeting Adjourned**