Food and Drug Administration
Center for Biologics Evaluation and Research
Office of Vaccines Research and Review
166th Meeting of the Vaccines and Related Biological Products Advisory Committee
June 10, 2021
AGENDA

Topic: The Committee will meet in open session to discuss, in general, data needed to support authorization and/or licensure of COVID-19 vaccines for use in pediatric populations.

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 (15 min)** • **Ramachandra Naik, Ph.D.,** Biologist (Regulatory), Division of Vaccines and Related Product Applications, Office of Vaccines Research and Review, CBER, FDA –10 min • Q/A – 5 Min
9:15 a.m.	**CDC: Epidemiology of COVID-19 in the Pediatric Populations (20 min)** • **LCDR. Hannah Kirking, M.D.** Medical Epidemiologist, Division of Viral Diseases, Respiratory Viruses Branch, CDC – 15 min • Q/A - 5 min
9:35 a.m.	**CDC: Operational Aspects (20 min)** • **Shannon Stokley, DrPH** Associate Director for Science, NCIRD, CDC - 15 min • Q/A - 5 min
9:55 a.m.	**Post-Authorization Surveillance Activities (30 min)** • **Steven Anderson, Ph.D.** Director, Office of Biostatistics and Epidemiology, CBER, FDA – 10 min

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	COVID-19 Vaccine Safety Updates • **CAPT. Tom Shimabukuro, M.D. M.PH. M.B.A.** Deputy Director, Immunization Safety Office, CDC – 10 min • Q/A - 10 min
10:25 a.m.	**BREAK** (10 minutes)
10:35 a.m.	**FDA Presentation – Considerations on Data to Support Licensure and Emergency Use Authorization of COVID-19 Vaccines for Use in Pediatric Populations (40 min)** • **Doran Fink, M.D., Ph.D.,** Deputy Director – Clinical, Division of Vaccines and Related Products Applications, Office of Vaccines Research and Review, CBER, FDA- 30 min • Q/A - 10 min
11:15 a.m.	**Additional Q & A Session (30 min)**
11:45 a.m.	**Industry Perspective: Considerations for COVID-19 Vaccine Pediatric Trials (15 min)** • **Phyllis Arthur, M.B.A.** Vice President, Infectious Diseases and Emerging Science Policy, Biotechnology Innovation Organization (BIO), Washington DC - 10 min • Q/A – 5 min
12:00 p.m.	**Lunch (30 min)**
12:30 p.m.	**Open Public Hearing (OPH) (60 min)**
1:30 p.m.	**Break (10 min)**
1:40 p.m.	**Committee Discussion (120 min)**
3:40 p.m.	**Meeting Adjourned - DFO**