

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.	<p><u>Opening Remarks: Call to Order and Welcome (10 min)</u></p> <p>Arnold Monto, M.D. Acting Chair, VRBPAC Professor of Public Health and Epidemiology, University of Michigan</p> <p><u>Administrative Announcements, Roll Call, Introduction of Committee, Conflict of Interest Statement (20 min)</u></p> <p>Prabhakara Atreya, Ph.D. Acting Designated Federal Officer, VRBPAC Director, Division Scientific Advisors and Consultants, CBER, FDA</p>
9:00 a.m.	<p><u>FDA Introduction (30 min including Q &A)</u></p> <p><u>Welcome (5 Min)</u></p> <ul style="list-style-type: none"> • Peter Marks, M.D. Ph.D. Center Director, CBER, FDA <p><u>Introduction of the Topic (10 Min)</u></p> <ul style="list-style-type: none"> • 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 <p><u>Background (10 Min)</u></p> <ul style="list-style-type: none"> • 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.	<p><u>CDC Presentations TBD (60 Min including Q &A)</u></p> <p><u>Epidemiology of COVID-19 in Children (20 Min)</u></p> <ul style="list-style-type: none"> • Fiona Havers, M.D. Medical Officer, Division of Viral Diseases

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	<p>National Center for Immunization and Respiratory Diseases (NCIRD) Centers for Disease Control and Prevention (CDC)</p> <ul style="list-style-type: none"> • Q/A - 10 min <p>Known safety signals (Myocarditis in adolescents and young adults) (20 Min)</p> <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • Q/A - 10 min
10:30 a.m.	<u>BREAK (15 min)</u>
10:45 a.m.	<p><u>Sponsor Presentation (50 Min including Q&A)</u></p> <p>BNT162b2 (Pfizer-BioNTech COVID-19 Vaccine) – Request for Emergency Use Authorization for Individuals 5 to < 12 Years of Age</p> <ul style="list-style-type: none"> • 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.	<p><u>FDA Presentation (50 min including Q&A)</u></p> <ul style="list-style-type: none"> • Leslie Ball, M.D. (30 min) Medical Officer, Clinical Review Branch 1, Division of Vaccines and Related Product Applications (DVRPA) Office of Vaccines Research and Review (OVRR), CBER, FDA • Q/A – (5 Min) • Benefit-Risk Analysis (10 min) Hong Yang, Ph.D. Senior Advisor for Benefit-Risk Assessment Office of Biostatistics and Epidemiology (OBE), CBER, FDA • Q/A – 5 min

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12:25 p.m.	<u>Lunch (35 min)</u>
1:00 p.m.	<u>Open Public Hearing (60 min)</u>
2:00 p.m.	<u>Break (10 Min)</u>
2:10 p.m.	<u>Additional Q & A regarding Sponsor and FDA presentations (45 min)</u>
2:55 p.m.	<u>Committee Discussion and Voting (125 min)</u>
5:00 p.m.	<u>Meeting Adjourned</u>