

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

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

	<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
<p>10:30 a.m.</p>	<p><u>BREAK (15 min)</u></p>
<p>10:45 a.m.</p>	<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
<p>11:35 a.m.</p>	<p><u>FDA Presentations (50 min including Q&A)</u></p> <ul style="list-style-type: none"> • <u>FDA review of Pfizer-BioNTech Submission (20 min)</u> 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 • <u>Post-Authorization Evaluation (5 min)</u> Hui-Lee Wong, Ph.D. Associate Director for Innovation and Development Office of Biostatistics and Epidemiology (OBE), CBER, FDA • <u>Benefit-Risk Analysis (20 min)</u> Hong Yang, Ph.D. Senior Advisor for Benefit-Risk Assessment

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

	Office of Biostatistics and Epidemiology (OBE), CBER, FDA <ul style="list-style-type: none">• Q/A – 5 min
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>