

**FOOD AND DRUG ADMINISTRATION (FDA)  
Center for Biologics Evaluation and Research (CBER)  
174<sup>th</sup> Meeting of the Vaccines and Related Biological Products  
Advisory Committee  
Silver Spring, MD  
June 14-15, 2022  
AGENDA**

**June 14, 2022**

**Topic 1:** The Committee will meet in open session to discuss amending the emergency use authorization (EUA) of the Moderna COVID-19 Vaccine to include the prevention of COVID-19 in children and adolescents 6 years through 17 years of age

Time	Presentation/Presenter
8:30 a.m.	<p><b><u>Opening Remarks: Call to Order and Welcome (5 Min)</u></b></p> <p>Arnold Monto, M.D. Acting Chair, VRBPAC Emeritus Professor of Public Health and Epidemiology, University of Michigan</p> <p><b><u>Administrative Announcements, Roll Call, Introduction of Committee, Conflict of Interest Statement (20 Min)</u></b></p> <p>Prabhakara Atreya, Ph.D., Director, Acting DFO, VRBPAC and Sussan Paydar, Ph.D. Alt. DFO, VRBPAC Division Scientific Advisors and Consultants, CBER, FDA</p>
8:55 a.m.	<p><b><u>FDA Introduction (20 Min)</u></b></p> <p><b>Welcome (5 Min)</b></p> <ul style="list-style-type: none"> <li>• Peter Marks, M.D. Ph.D. Director, Center for Biologics Evaluation and Research (CBER)</li> </ul> <p><b>Introduction to Topic 1: Moderna COVID-19 Vaccine: Request for Emergency Use Authorization (EUA) Amendment, Use of a 2-Dose Primary Series in Children and Adolescents 6 years through 17 Years of Age (10 Min)</b></p> <ul style="list-style-type: none"> <li>• Sudhakar Agnihothram, B. Pharm. Ph.D. Primary Reviewer Division of Vaccines and Related Products Applications (DVRPA) Office of Vaccines Research and Review (OVRR), CBER</li> <li>• Q&amp; A – 5 Min</li> </ul>

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<b>9:15 a.m.</b>	<p><b><u>Centers for Disease Control and Prevention (CDC) Presentations (55 Min)</u></b></p> <p><b>COVID-19 Epidemiology and Disease Burden in Infants, Children and Adolescents (15 Min)</b></p> <ul style="list-style-type: none"> <li>• Katherine E. Fleming-Dutra, M.D.  Medical Officer  COVID-19 Vaccine Policy Unit  National Center for Immunization and Respiratory Diseases  CDC</li> </ul> <p><b>Update on mRNA COVID-19 Vaccine Effectiveness (15 Min)</b></p> <ul style="list-style-type: none"> <li>• Ruth Link-Gelles, PH.D.M.PH.  LCDR, U.S. Public Health Service  COVID-19 Vaccine Effectiveness Program Lead  Division of Viral Diseases, CDC</li> </ul> <p><b>Update on mRNA COVID-19 Vaccine Post Authorization Safety Assessment in Pediatric Age Groups (15 Min)</b></p> <ul style="list-style-type: none"> <li>• Tom Shimabukuro, M.D. M.PH.M.B.A.  Captain, U.S. Public Health Service  Director  Immunization Safety Office, CDC</li> <li>• Q &amp; A: 10 Min</li> </ul>
<b>10:10 a.m.</b>	<p><b><u>FDA Presentation</u></b></p> <p><b>Safety Surveillance of COVID-19 Vaccines in Children and Adolescents (15 min)</b></p> <ul style="list-style-type: none"> <li>• Hui-Lee Wong, Ph.D.  Associate Director for Innovation and Development  Office of Biostatistics and Pharmacovigilance (OBPV), CBER</li> <li>• Q &amp; A: 5 Min</li> </ul>

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<b>10:30 a.m.</b>	<b>Break 10 Min</b>
<b>10:40 a.m.</b>	<p><b><u>Sponsor Presentation: (60 Min including Q&amp;A)</u></b></p> <p><b>mRNA-1273 (Moderna COVID-19 Vaccine) – Request for Emergency Use Authorization in Individuals 6 - 17 Years of Age (50 Min)</b></p> <ul style="list-style-type: none"> <li>• Carla Vinals, Ph.D.- Vice President, Regulatory Affairs Strategy, Infectious Diseases, ModernaTX, Inc.</li> <li>• Evan Anderson, M.D., FAAP - Associate Professor, Pediatrics and Medicine, Emory University School of Medicine</li> <li>• Jacqueline Miller, M.D., FAAP - Senior Vice President, Therapeutic Area Head, Infectious Diseases, ModernaTX, Inc.</li> <li>• Rituparna Das, M.D., Ph.D. - Vice President, Clinical Development, COVID-19 Vaccines, ModernaTX, Inc.</li> <li>• Q &amp; A: 10 Min</li> </ul>
<b>11:40 a.m.</b>	<p><b><u>FDA presentations (50 Min)</u></b></p> <p><b>FDA Review of Effectiveness and Safety of Moderna COVID-19 Vaccine in Children and Adolescents 6 through 17 Years of Age (50 min)</b></p> <ul style="list-style-type: none"> <li>• Rachel Zhang, M.D. Team Leader Clinical Review Staff, Immediate Office of Director DVRPA, OVRP, CBER, FDA</li> </ul>
<b>12:30 p.m.</b>	<b><u>Lunch (30 Min)</u></b>

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<b>1:00 p.m.</b>	<b><u>Open Public Hearing (60 Min)</u></b>
<b>2:00 p.m.</b>	<b><u>Additional Q &amp; A for CDC, FDA and Sponsor Presenters (60 Min)</u></b>
<b>3:00 p.m.</b>	<b><u>Break (10 Min)</u></b>
<b>3:10 p.m.</b>	<b><u>Committee Discussion and Voting (110 Min)</u></b>
<b>5:00 p.m.</b>	<b><u>Meeting Adjourned - DFO</u></b>

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**June 15, 2022**

**Topic 2:** The Committee will meet in open session to discuss amending the EUA of the Moderna COVID-19 Vaccine to include the prevention of COVID-19 in infants and children 6 months through 5 years of age, and also to discuss amending the EUA of the Pfizer-BioNTech COVID -19 Vaccine to include the prevention of COVID-19 in infants and children 6 months through 4 years of age

<b>Time</b>	<b>Presentation/Presenter</b>
<b>8:30 a.m.</b>	<p><b><u>Opening Remarks: Call to Order and Welcome (5 Min)</u></b></p> <p>Arnold Monto, M.D. Acting Chair, VRBPAC Emeritus Professor of Public Health and Epidemiology, University of Michigan</p> <p><b><u>Administrative Announcements, Roll Call, Introduction of Committee, Conflict of Interest Statement (20 Min)</u></b></p> <p>Prabhakara Atreya, Ph.D., Director, Acting DFO, VRBPAC and Sussan Paydar, Ph.D. Alt. DFO, VRBPAC Division Scientific Advisors and Consultants, CBER, FDA</p>
<b>8:55 a.m.</b>	<p><b><u>FDA Introduction (20 Min)</u></b></p> <p><b>Welcome (5 Min)</b></p> <ul style="list-style-type: none"> <li>• Peter Marks, M.D. Ph.D. Director, Center for Biologics Evaluation and Research (CBER)</li> </ul> <p><b>Moderna COVID-19 Vaccine: Request for Emergency Use Authorization (EUA) Amendment, use of a 2-Dose Primary Series in Infants and Children 6 Months through 5 Years of Age, and</b></p> <p><b>Pfizer-BioNTech COVID-19 Vaccine: Request for EUA Amendment, Use of a 3-Dose Primary Series in Infants and Children 6 Months through 4 Years of Age (10 Min)</b></p> <ul style="list-style-type: none"> <li>• Sudhakar Agnihothram, Ph.D. and</li> <li>• Ramachandra Naik, Ph.D. Division of Vaccines and Related Products Applications (DVRPA), OVRR, CBER, FDA</li> </ul>

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	<ul style="list-style-type: none"> <li>• Q &amp; A – 5 Min</li> </ul>
<b>9:15 a.m.</b>	<p><b><u>Sponsor Moderna Presentation: (45 Min including Q&amp;A)</u></b></p> <p><b>mRNA-1273 (Moderna COVID-19 Vaccine) – Request for Emergency Use Authorization for Use in Individuals 6 Months through 5 Years of Age (35 Min)</b></p> <ul style="list-style-type: none"> <li>• Carla Vinals, Ph.D.- Vice President, Regulatory Affairs Strategy, Infectious Diseases, ModernaTX, Inc.</li> <li>• Evan Anderson, M.D., FAAP - Associate Professor, Pediatrics and Medicine, Emory University School of Medicine</li> <li>• Jacqueline Miller, M.D., FAAP - Senior Vice President, Therapeutic Area Head, Infectious Diseases, ModernaTX, Inc.</li> <li>• Rituparna Das, M.D., Ph.D. - Vice President, Clinical Development, COVID-19 Vaccines, ModernaTX, Inc.</li> <li>• Q &amp; A: 10 Min</li> </ul>
<b>10:00 a.m.</b>	<p><b><u>FDA presentation (45 Min including Q &amp;A)</u></b></p> <p><b>FDA Review of Effectiveness and Safety of Moderna COVID-19 Vaccine in Infants and Children 6 Months through 5 Years of Age (35 Min)</b></p> <ul style="list-style-type: none"> <li>• Robin Wisch, M.D. Medical Officer Clinical Review Staff, Immediate Office of Director, DVRPA, OVRP, CBER, FDA</li> <li>• Q &amp; A- 10 Min</li> </ul>
<b>10:45 a.m.</b>	<b><u>Break (15 Min)</u></b>
<b>11:00 a.m.</b>	<b><u>Sponsor Pfizer Presentation: (45 Min including Q&amp;A)</u></b>

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	<p><b>BNT162b2 (Pfizer-BioNTech COVID-19 Vaccine) – Request for Emergency Use Authorization for Use in Infants and Children 6 Months through 4 Years of Age (35 Min)</b></p> <ul style="list-style-type: none"> <li>• William C. Gruber, MD, FAAP, FIDSA, FPIDS Senior Vice President, Vaccine Clinical Research and Development, Pfizer Inc.</li> <li>• Q &amp; A: 10 Min</li> </ul>
<b>11:45 a.m.</b>	<p><b><u>FDA presentation (45 min including Q &amp;A)</u></b></p> <p><b>FDA Review of Effectiveness and Safety of Pfizer-BioNTech COVID-19 Vaccine in Infants and Children 6 Months through 4 Years of Age (35 Min)</b></p> <ul style="list-style-type: none"> <li>• Susan Wollersheim, M.D. Medical Officer, Clinical Review Branch 1 DVRPA, OVRP, CBER</li> <li>• Q &amp; A- 10 Min</li> </ul>
<b>12:30 p.m.</b>	<b><u>Lunch (30 Min)</u></b>
<b>1:00 p.m.</b>	<b><u>Open Public Hearing (60 Min)</u></b>
<b>2:00 p.m.</b>	<b><u>Additional Q &amp; A for FDA and Sponsor Presenters – Moderna COVID-19 Vaccine (25 Min)</u></b>
<b>2:25 p.m.</b>	<b><u>Committee Discussion and Voting – Moderna COVID-19 Vaccine (60 Min)</u></b>
<b>3:25 p.m.</b>	<b><u>Break (10 Min)</u></b>
<b>3:35 p.m.</b>	<b><u>Additional Q &amp; A for FDA and Sponsor Presenters – Pfizer-BioNTech COVID-19 Vaccine (25 Min)</u></b>

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<b>4:00 p.m.</b>	<b><u>Committee Discussion and Voting – Pfizer-BioNTech COVID-19 Vaccine (60 Min)</u></b>
<b>5:00 p.m.</b>	<b><u>Meeting Adjourned - DFO</u></b>