FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
174th 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.	**Opening Remarks: Call to Order and Welcome (5 Min)** Arnold Monto, M.D. Acting Chair, VRBPAC Emeritus 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., Director, Acting DFO, VRBPAC and Sussan Paydar, Ph.D. Alt. DFO, VRBPAC Division Scientific Advisors and Consultants, CBER, FDA
8:55 a.m.	**FDA Introduction (20 Min)** **Welcome (5 Min)** • Peter Marks, M.D. Ph.D. Director, Center for Biologics Evaluation and Research (CBER) **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)** • Sudhakar Agnihothram, B. Pharm. Ph.D. Primary Reviewer Division of Vaccines and Related Products Applications (DVRPA) Office of Vaccines Research and Review (OVRR), CBER • Q& A – 5 Min

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9:15 a.m.	**<u>Centers for Disease Control and Prevention (CDC) Presentations (55 Min)</u>** **COVID-19 Epidemiology and Disease Burden in Infants, Children and Adolescents (15 Min)** • Katherine E. Fleming-Dutra, M.D. Medical Officer COVID-19 Vaccine Policy Unit National Center for Immunization and Respiratory Diseases CDC **Update on mRNA COVID-19 Vaccine Effectiveness (15 Min)** • Ruth Link-Gelles, PH.D.M.PH. LCDR, U.S. Public Health Service COVID-19 Vaccine Effectiveness Program Lead Division of Viral Diseases, CDC **Update on mRNA COVID-19 Vaccine Post Authorization Safety Assessment in Pediatric Age Groups (15 Min)** • Tom Shimabukuro, M.D. M.PH.M.B.A. Captain, U.S. Public Health Service Director Immunization Safety Office, CDC • Q & A: 10 Min
10:10 a.m.	**<u>FDA Presentation</u>** **Safety Surveillance of COVID-19 Vaccines in Children and Adolescents (15 min)** • Hui-Lee Wong, Ph.D. Associate Director for Innovation and Development Office of Biostatistics and Pharmacovigilance (OBPV), CBER • Q & A: 5 Min

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10:30 a.m.	**Break 10 Min**
10:40 a.m.	**Sponsor Presentation: (60 Min including Q&A)** **mRNA-1273 (Moderna COVID-19 Vaccine) – Request for Emergency Use Authorization in Individuals 6 - 17 Years of Age (50 Min)** • Carla Vinals, Ph.D.- Vice President, Regulatory Affairs Strategy, Infectious Diseases, ModernaTX, Inc. • Evan Anderson, M.D., FAAP - Associate Professor, Pediatrics and Medicine, Emory University School of Medicine • Jacqueline Miller, M.D., FAAP - Senior Vice President, Therapeutic Area Head, Infectious Diseases, ModernaTX, Inc. • Rituparna Das, M.D., Ph.D. - Vice President, Clinical Development, COVID-19 Vaccines, ModernaTX, Inc. • Q & A: 10 Min
11:40 a.m.	**FDA presentations (50 Min)** **FDA Review of Effectiveness and Safety of Moderna COVID-19 Vaccine in Children and Adolescents 6 through 17 Years of Age (50 min)** • Rachel Zhang, M.D. Team Leader Clinical Review Staff, Immediate Office of Director DVRPA, OVRR, CBER, FDA
12:30 p.m.	**Lunch (30 Min)**

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

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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

Time	Presentation/Presenter
8:30 a.m.	**Opening Remarks: Call to Order and Welcome (5 Min)** Arnold Monto, M.D. Acting Chair, VRBPAC Emeritus 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., Director, Acting DFO, VRBPAC and Sussan Paydar, Ph.D. Alt. DFO, VRBPAC Division Scientific Advisors and Consultants, CBER, FDA
8:55 a.m.	**FDA Introduction (20 Min)** **Welcome (5 Min)** • Peter Marks, M.D. Ph.D. Director, Center for Biologics Evaluation and Research (CBER) **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** **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)** • Sudhakar Agnihothram, Ph.D. and • Ramachandra Naik, Ph.D. Division of Vaccines and Related Products Applications (DVRPA), OVRR, CBER, FDA

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	• Q & A – 5 Min
9:15 a.m.	**Sponsor Moderna Presentation: (45 Min including Q&A)** **mRNA-1273 (Moderna COVID-19 Vaccine) – Request for Emergency Use Authorization for Use in Individuals 6 Months through 5 Years of Age (35 Min)** • Carla Vinals, Ph.D.- Vice President, Regulatory Affairs Strategy, Infectious Diseases, ModernaTX, Inc. • Evan Anderson, M.D., FAAP - Associate Professor, Pediatrics and Medicine, Emory University School of Medicine • Jacqueline Miller, M.D., FAAP - Senior Vice President, Therapeutic Area Head, Infectious Diseases, ModernaTX, Inc. • Rituparna Das, M.D., Ph.D. - Vice President, Clinical Development, COVID-19 Vaccines, ModernaTX, Inc. • Q & A: 10 Min
10:00 a.m.	**FDA presentation (45 Min including Q &A)** **FDA Review of Effectiveness and Safety of Moderna COVID-19 Vaccine in Infants and Children 6 Months through 5 Years of Age (35 Min)** • Robin Wisch, M.D. Medical Officer Clinical Review Staff, Immediate Office of Director, DVRPA, OVRR, CBER, FDA • Q & A- 10 Min
10:45 a.m.	**Break (15 Min)**
11:00 a.m.	**Sponsor Pfizer Presentation: (45 Min including Q&A)**

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	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) • William C. Gruber, MD, FAAP, FIDSA, FPIDS Senior Vice President, Vaccine Clinical Research and Development, Pfizer Inc. • Q & A: 10 Min
11:45 a.m.	**FDA presentation (45 min including Q &A)** **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)** • Susan Wollersheim, M.D. Medical Officer, Clinical Review Branch 1 DVRPA, OVRR, CBER • Q & A- 10 Min
12:30 p.m.	**Lunch (30 Min)**
1:00 p.m.	**Open Public Hearing (60 Min)**
2:00 p.m.	**Additional Q & A for FDA and Sponsor Presenters – Moderna COVID-19 Vaccine (25 Min)**
2:25 p.m.	**Committee Discussion and Voting – Moderna COVID-19 Vaccine (60 Min)**
3:25 p.m.	**Break (10 Min)**
3:35 p.m.	**Additional Q & A for FDA and Sponsor Presenters – Pfizer-BioNTech COVID-19 Vaccine (25 Min)**

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