FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
178th Meeting of the Vaccines and Related Biological Products Advisory Committee
January 26, 2023
AGENDA

Topic: The committee will meet in open session to discuss future vaccination regimens addresing COVID-19.

EST 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 (15 Min)** Sussan Paydar, Ph.D. Designated Federal Officer, VRBPAC Division Of Scientific Advisors and Consultants Center for Biologics Evaluation and Research (CBER), FDA
8:50 a.m.	**FDA Introduction (20 Min)** **Welcome (5 Min)** • Peter Marks, M.D. Ph.D. Center Director, CBER, FDA **Considerations for Updating Boosters and Whether and How Primary COVID-19 Vaccine Strain Composition Should be Modified (10 Min)** • David Kaslow, M.D. Director Office of Vaccines Research and Review (OVRR), CBER, FDA Q/A – 5 Min
9:10 a.m.	**CDC Presentation (30 Min total including Q/A)** **Update on Current Epidemiology of the COVID-19 Pandemic and SARS-CoV-2 Variants (25 Min)** • CDR Heather Scobie, Ph.D., MPH Surveillance and Analytics Team Lead (Acting) National Center for Immunization and Respiratory Diseases Centers for Disease Control and Prevention (CDC)

	Q/A – 5 Min
9:40 a.m.	**<u>CDC Presentations (45 Min total including Q/A)</u>** **Update on Original COVID-19 Vaccine and COVID-19 Vaccine Bivalent Effectiveness and Safety (40 Min)** • Ruth Link-Gelles, PH.D., M.PH. (20 min) LCDR, U.S. Public Health Service COVID-19 Vaccine Effectiveness Program Lead National Center for Immunization and Respiratory Diseases, CDC • Tom Shimabukuro, M.D., M.PH., M.B.A. (5 min) Captain, U.S. Public Health Service Director Immunization Safety Office, CDC • Nicola Klein, M.D., Ph.D. (15 min) Director, Kaiser Permanente Vaccine Study Center Professor, Department of Health Systems Science Kaiser Permanente Bernard J. Tyson School of Medicine Q/A – 5 Min
10:25 a.m.	**<u>FDA Presentation (30 Min Total including Q/A)</u>** **Update on Original COVID-19 Vaccine and COVID-19 Vaccine, Bivalent Effectiveness and Safety (25 min)** • Richard Forshee, Ph.D. Deputy Director Office of Biostatistics and Pharmacovigilance, CBER, FDA Q/A – 5 Min
10:55 a.m.	**<u>NIH Presentation (25 Min Total including Q/A)</u>** **Evaluation of Improved Generation COVID-19 Vaccines (20 min)** • John Beigel, M.D. Associate Director for Clinical Research Division of Microbiology and Infectious Diseases

	National Institute of Allergy and Infectious Diseases National Institutes of Health Q/A – 5 min
11:20 a.m.	**Break (10 min)**
11:30 a.m.	**Moderna Presentation (30 Min Total including Q/A)** **Introduction: Moderna COVID-19 Bivalent Vaccines Primary Series and Booster** Antonella Lozito, PharmD Executive Director, Regulatory Affairs - Infectious Disease Moderna, Inc. **Clinical Data with Omicron-Containing mRNA-1273 Bivalent Vaccines** Rituparna Das, M.D., Ph.D. Vice President, Clinical Development, COVID-19 Vaccines Moderna, Inc. **Real-World Effectiveness Data** Rituparna Das, M.D., Ph.D. Vice President, Clinical Development, COVID-19 Vaccines Moderna, Inc. **Preclinical Results from Authorized and Investigational Multivalent Vaccines** Darin Edwards, Ph.D. Senior Director of Immunology Infectious Disease Group Moderna, Inc. **Summary and Conclusions** Rituparna Das, M.D., Ph.D. Vice President, Clinical Development, COVID-19 Vaccines Moderna, Inc. Q/A –5 Min

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12:00 p.m.	**Pfizer presentation (30 Min Total including Q/A)** **Pfizer/BioNTech COVID-19 Variant Vaccines (25 Min)** Kena A. Swanson, Ph.D. Vice President, Viral Vaccines, Vaccine Research and Development, Pfizer Inc. Q/A – 5 Min
12:30 p.m.	**Novavax presentation (30 Min Total including Q/A)** **Novavax Vaccine Regimens Addressing COVID-19 (25 Min)** Dr. Filip Dubovsky, M.D. Executive Vice President and Novavax Chief Medical Officer - Novavax Q/A – 5 Min
1:00 p.m.	**Lunch (30 Min)**
1:30 p.m.	**Open Public Hearing (60 Min)**
2:30 p.m.	**FDA Presentation (30 Min Total including Q/A)** **FDA Considerations for Potential Changes to COVID-19 Vaccine Strain Composition (25 Min)** • Jerry Weir, Ph.D. Director, Division of Viral Products Office of Vaccines Research and Review, CBER, FDA Q/A - 5 Min
3:00 p.m.	**Break (10 Min)**
3:10 p.m.	**Additional Q & A for CDC, FDA and Sponsor Presenters (20 Min)**

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3:30 p.m.	**Committee Discussion and Voting (120 Min)**
5:30 p.m.	**Meeting Adjourned - DFO**