

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 addressing COVID-19.

EST Time	Presentation/Presenter
8:30 a.m.	<p><u>Opening Remarks: Call to Order and Welcome (5 Min)</u></p> <p>Arnold Monto, M.D. Acting Chair, VRBPAC Emeritus Professor of Public Health and Epidemiology University of Michigan</p> <p><u>Administrative Announcements, Roll Call, Introduction of Committee, Conflict of Interest Statement (15 Min)</u></p> <p>Sussan Paydar, Ph.D. Designated Federal Officer, VRBPAC Division Of Scientific Advisors and Consultants Center for Biologics Evaluation and Research (CBER), FDA</p>
8:50 a.m.	<p><u>FDA Introduction (20 Min)</u></p> <p>Welcome (5 Min)</p> <ul style="list-style-type: none">• Peter Marks, M.D. Ph.D. Center Director, CBER, FDA <p>Considerations for Updating Boosters and Whether and How Primary COVID-19 Vaccine Strain Composition Should be Modified (10 Min)</p> <ul style="list-style-type: none">• David Kaslow, M.D. Director Office of Vaccines Research and Review (OVRR), CBER, FDA <p>Q/A – 5 Min</p>
9:10 a.m.	<p><u>CDC Presentation (30 Min total including Q/A)</u></p> <p>Update on Current Epidemiology of the COVID-19 Pandemic and SARS-CoV-2 Variants (25 Min)</p> <ul style="list-style-type: none">• 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)

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	Q/A – 5 Min
9:40 a.m.	<p><u>CDC Presentations (45 Min total including Q/A)</u></p> <p>Update on Original COVID-19 Vaccine and COVID-19 Vaccine Bivalent Effectiveness and Safety (40 Min)</p> <ul style="list-style-type: none">• 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 <p>Q/A – 5 Min</p>
10:25 a.m.	<p><u>FDA Presentation (30 Min Total including Q/A)</u></p> <p>Update on Original COVID-19 Vaccine and COVID-19 Vaccine, Bivalent Effectiveness and Safety (25 min)</p> <ul style="list-style-type: none">• Richard Forshee, Ph.D. Deputy Director Office of Biostatistics and Pharmacovigilance, CBER, FDA <p>Q/A – 5 Min</p>
10:55 a.m.	<p><u>NIH Presentation (25 Min Total including Q/A)</u></p> <p>Evaluation of Improved Generation COVID-19 Vaccines (20 min)</p> <ul style="list-style-type: none">• John Beigel, M.D. Associate Director for Clinical Research Division of Microbiology and Infectious Diseases

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

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12:00 p.m.	<p>Pfizer presentation (30 Min Total including Q/A)</p> <p><u>Pfizer/BioNTech COVID-19 Variant Vaccines (25 Min)</u></p> <p>Kena A. Swanson, Ph.D. Vice President, Viral Vaccines, Vaccine Research and Development, Pfizer Inc.</p> <p>Q/A – 5 Min</p>
12:30 p.m.	<p>Novavax presentation (30 Min Total including Q/A)</p> <p><u>Novavax Vaccine Regimens Addressing COVID-19 (25 Min)</u></p> <p>Dr. Filip Dubovsky, M.D. Executive Vice President and Novavax Chief Medical Officer - Novavax</p> <p>Q/A – 5 Min</p>
1:00 p.m.	<p><u>Lunch (30 Min)</u></p>
1:30 p.m.	<p><u>Open Public Hearing (60 Min)</u></p>
2:30 p.m.	<p><u>FDA Presentation (30 Min Total including Q/A)</u></p> <p><u>FDA Considerations for Potential Changes to COVID-19 Vaccine Strain Composition (25 Min)</u></p> <ul style="list-style-type: none">• Jerry Weir, Ph.D. Director, Division of Viral Products Office of Vaccines Research and Review, CBER, FDA <p>Q/A - 5 Min</p>
3:00 p.m.	<p><u>Break (10 Min)</u></p>
3:10 p.m.	<p><u>Additional Q & A for CDC, FDA and Sponsor Presenters (20 Min)</u></p>

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3:30 p.m.	<u>Committee Discussion and Voting (120 Min)</u>
5:30 p.m.	<u>Meeting Adjourned - DFO</u>