

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
171st Meeting of the Vaccines and Related Biological Products
Advisory Committee
April 6, 2022
DRAFT AGENDA

Topic: The committee will meet in open session to discuss considerations for COVID-19 vaccine booster doses and the process for COVID-19 vaccine strain selection to address current and emerging variants

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 (15 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>Introduction to the Topic: COVID-19 vaccine booster vaccination (10 min)</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 (OVRP), CBER, FDA
9:15 a.m.	<p><u>Update on the Epidemiology of COVID-19 Variants (35 min)</u></p> <ul style="list-style-type: none"> • CDR Heather Scobie, PhD, M.PH. (30 min) Deputy Team Lead, Surveillance and Analytics Epidemiology Task Force COVID-19 Emergency Response Centers for Disease Control and Prevention (CDC) • Q/A – 5 min
9:50 a.m.	<p><u>COVID-19 Vaccine Effectiveness in Children and Adults (25 min)</u></p> <ul style="list-style-type: none"> • LCDR.Ruth Link-Gelles, Ph.D. (20 min) <p>Epidemiologist, Division of Viral Diseases National Center for Immunization and Respiratory Diseases (NCIRD)</p>

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	<p>Centers for Disease Control and Prevention (CDC)</p> <ul style="list-style-type: none"> • Q/A – 5 min
10:20 a.m.	<p>Israeli Experience with Fourth Booster Doses in Older Adults (20 min)</p> <ul style="list-style-type: none"> • Sharon Alroy-Preis, M.D. M.PH.M.B.A – (10 min) Director, Public Health Services Ministry of Health, Jerusalem, Israel • Ron Milo. Ph.D. - (5 Min) Professor, Dept. of Plant and Environmental Sciences, Dean of Education, Weissman Institute, Rehovot, Israel <p>Q/A – 5 min</p>
10:40 a.m.	<p>Break (10 min)</p>
10:50 a.m.	<p>Predicting Future SARS-CoV-2 Variants (30 min)</p> <ul style="list-style-type: none"> • John Beigel, M.D. (10 min) Associate Director for Clinical Research Division of Microbiology and Infectious Diseases Office of the Director, NIAID, NIH • Trevor Bedford, Ph.D. (10 Min) Professor, Fred Hutchinson Cancer Research Center Investigator, Howard Hughes Medical Inst. Seattle • Q &A – 10 Min
11:20 a.m.	<p>Modeling of Future U.S. COVID-19 Outbreaks (30 min)</p> <ul style="list-style-type: none"> • Christopher Murray, M.D. D.Phil. (15 Min) Professor and Chair Department of Health Metrics Sciences Director, Institute for Health Metrics and Evaluation (IHME) • Ali H. Mokdad, Ph.D. (5 min) Professor, Health Metrics Sciences Chief Strategy Officer, Population Health Institute for Health Metrics and Evaluation (IHME) School of Medicine, Washington University • Q &A – 10 Min

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11:50 a.m.	WHO Perspective on Variants for COVID-19 Vaccine Composition (20 min) <ul style="list-style-type: none"> • Kanta Subbarao, M.D. M.PH. (15 min) Director, WHO Collaborating Center for Reference and Research on Influenza, Peter Doherty Institute for Infection and Immunity Melbourne, Australia • Q &A – 5 min
12:10 p.m.	Perspective on Variant Vaccine Development and Production (20 min) <ul style="list-style-type: none"> • Robert Johnson, Ph.D. (15 min) Deputy Assistant Secretary Director, Medical Countermeasure Programs Biomedical Advanced Research and Development Authority (BARDA) • Q &A – 5 min
12:30 p.m.	Proposed Framework for Addressing Future COVID-19 Outbreaks (30 min) <ul style="list-style-type: none"> • Jerry Weir, Ph.D. (20 min) Position Office of Vaccines Research and Review (OVRR), CBER, FDA • Q/A – 10 min
1:00 p.m.	<u>Lunch (30 min)</u>
1:30 p.m.	<u>Open Public Hearing (60 min)</u>
2:30 p.m.	<u>Committee Discussion of Questions (150 min)</u>
5:00 p.m.	<u>Meeting Adjourned</u>