

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
169th Meeting of the Vaccines and Related Biological Products
Advisory Committee
October 14-15, 2021
DRAFT AGENDA

October 14, 2021: Topic 1: The committee will meet in open session to discuss the EUA of the Moderna COVID-19 mRNA Vaccine for the administration of an booster dose, following completion of the primary series, in individuals 18 years of age and older.

Time	Presentation/Presenter
8:30 a.m.	<p><u>Opening Remarks: Call to Order and Welcome (10 min)</u> 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> 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 (30 min)</u></p> <p><u>Introduction of the Topic (10 Min)</u></p> <ul style="list-style-type: none"> • Peter Marks, M.D. Ph.D. Center Director CBER, FDA <p><u>Background (15 Min)</u></p> <ul style="list-style-type: none"> • Sudhakar Agnihothram, Ph.D. Division of Vaccines and Related Product Applications (DVRPA), OVRP, CBER, FDA • Q/A – 5 Min
9:30 a.m.	<p><u>Presentation of Data Relevant to the Need for Boosters (60 Min)</u></p> <p>Presentation of Updated Israeli Vaccination Data (40 Min)</p> <ul style="list-style-type: none"> • Speaker 1: Sharon Alroy, M.D., M.P.H, M.B.A., Director of Public Health Services, Ministry of Health Israel • Speaker 2: Ron Milo, Ph.D., Professor, Weitzman Institute, Israel • Q/A - 20 min
10:30 am	<p><u>BREAK (15min)</u></p>

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10:45 am	<p><u>Sponsor Presentation (45 Min)</u></p> <p>Safety and Immunogenicity of a 50 µg Booster Dose of mRNA-1273 (Moderna COVID-19 Vaccine)</p> <ul style="list-style-type: none"> • Jacqueline Miller, MD ID Therapeutic Area Head, Moderna Therapeutics
11:30 am	<p><u>FDA Presentation (45 min)</u></p> <ul style="list-style-type: none"> • Tina Mongeau, M.D., M.P.H. Medical Officer Clinical Review Branch 1, DVRPA, OVRP, CBER • Hui-Lee Wong, Ph.D., Associate Director for Innovation Office of Biostatistics and Epidemiology, CBER, FDA • Richard Forshee, Ph.D., Acting Deputy Director Office of Biostatistics and Epidemiology, CBER, FDA • Q/A – 5 min
12:15 pm	<u>Lunch (30 min)</u>
12:45 pm	<u>Open Public Hearing (60 min)</u>
1:45 pm	<u>Break (15 Min)</u>
2:00 pm	<u>Additional Q & A regarding Sponsor and FDA presentations (45 min)</u>
2:45 pm	<u>Committee Discussion and Voting (120 min)</u>
4:45 pm	<u>Meeting Adjourned</u>