FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
167th Meeting of the Vaccines and Related Biological Products Advisory Committee
September 17, 2021
AGENDA

Topic: The committee will meet in open session to discuss Pfizer-BioNTech's supplemental Biologics License Application for administration of a third dose, or "booster" dose, of the COVID-19 vaccine, Comirnaty, in individuals 16 years of age and older.

Time	Presentation/Presenter
8:30 a.m.	**Opening Remarks: Call to Order and Welcome (10 min)** Arnold Monto, M.D. Acting Chair, VRBPAC 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. Acting Designated Federal Officer, VRBPAC Director, Division Scientific Advisors and Consultants, CBER, FDA
9:00 a.m.	**FDA Introduction (20 min)** **Welcome** • Peter Marks, M.D. Ph.D. Center Director, CBER, FDA **Application for Licensure of a Booster Dose of COMIRNATY, COVID-19 Vaccine, mRNA** • Marion Gruber, Ph.D., Director, Office of Vaccines Research and Review (OVRR), CBER, FDA **Comirnaty (COVID-19 Vaccine, mRNA) Supplemental Biologics License Application for a booster dose in individuals 16 years of age and older** • Ramachandra Naik, Ph.D., Biologist (Regulatory), Division of Vaccines and Related Product Applications (DVRPA), OVRR, CBER, FDA • Q/A – 5 Min
9:20 a.m.	**CDC: Updates to COVID-19 Epidemiology and COVID-19 Vaccines** • Sarah Oliver, M.D., M.S.P.H. Centers for Disease Control and Prevention Division of Viral Disease, National Center for Immunization and Respiratory Diseases • Q/A - 5 min **Real-world effectiveness of COVID-19 vaccines** • Jonathan Sterne, B.A., M.Sc., Ph.D. Professor of Medical Statistics and Epidemiology Bristol Medical School, University of Bristol, UK • Q/A – 5 min

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	Booster protection against confirmed infections and severe disease – data from Israel • Speaker 1: Sharon Alroy-Preis, M.D., M.P.H., M.B.A, Director of Public Health Services, Ministry of Health, Israel • Speaker 2: Ron Milo, Ph.D., Professor, Weizmann Institute, Israel • Q/A – 5 min
10:40 am	**BREAK**
10:45 am	**Sponsor Presentation** **BNT162b2 [COMIRNATY (COVID-19 Vaccine, mRNA)] Booster (Third) Dose** • Donna Boyce, MS, Senior Vice President, Global Regulatory Affairs Pfizer Inc. • William C. Gruber, MD, Senior Vice President, Vaccine Clinical Research and Development Pfizer Inc.
11:30 am	**FDA Review of Effectiveness and Safety of COMIRNATY (COVID-19 Vaccine, mRNA) Booster Dose Biologics License Application Supplement** • Joohee Lee, M.D., Medical Officer, Clinical Review Branch 1, DVRPA, OVRR, CBER, FDA
12:05 pm	**Lunch**
12:30 pm	**Open Public Hearing**
1:30 pm	**Break**
1:40 pm	**Q & A regarding Sponsor and FDA presentations**
2:25 pm	**Committee Discussion and Voting**
4:45 pm	**Meeting Adjourned**