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.

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<th>Time</th>
<th>Presentation/Presenter</th>
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<td>8:30 a.m.</td>
<td><strong>Opening Remarks: Call to Order and Welcome (10 min)</strong>&lt;br&gt;Arnold Monto, M.D. Acting Chair, VRBPAC&lt;br&gt;Professor of Public Health and Epidemiology, University of Michigan</td>
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<td><strong>Administrative Announcements, Roll Call, Introduction of Committee, Conflict of Interest Statement (20 min)</strong>&lt;br&gt;Prabhakara Atreya, Ph.D. Acting Designated Federal Officer, VRBPAC&lt;br&gt;Director, Division Scientific Advisors and Consultants, CBER, FDA</td>
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<td>9:00 a.m.</td>
<td><strong>FDA Introduction (20 min)</strong></td>
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<td><strong>Welcome</strong>&lt;br&gt;• Peter Marks, M.D. Ph.D. Center Director, CBER, FDA</td>
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<td><strong>Introduction of the Topic</strong>&lt;br&gt;• Marion Gruber, Ph.D., Director, Office of Vaccines Research and Review (OVRR), CBER, FDA</td>
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<td><strong>Background</strong>&lt;br&gt;• Ramachandra Naik, Ph.D., Biologist (Regulatory), Division of Vaccines and Related Product Applications (DVRPA), OVRR, CBER, FDA&lt;br&gt;• Q/A – 5 Min</td>
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<td>9:20 a.m.</td>
<td><strong>CDC: Epidemiology of pandemic CDC delta variant/breakthrough infections (15 min)</strong>&lt;br&gt;Sarah Oliver, M.D., M.S.P.H.&lt;br&gt;Centers for Disease Control and Prevention&lt;br&gt;Division of Viral Disease, National Center for Immunization and Respiratory Diseases&lt;br&gt;• Q/A - 5 min</td>
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<td><strong>Real-world effectiveness of COVID-19 vaccines (20 min)</strong>&lt;br&gt;Jonathan Sterne, B.A., M.Sc., Ph.D.&lt;br&gt;Professor of Medical Statistics and Epidemiology&lt;br&gt;Bristol Medical School, University of Bristol, UK&lt;br&gt;• Q/A – 5 min</td>
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**Booster protection against confirmed infections and severe disease – data from Israel (30 min)**
- Speaker 1: Sharon Elroy-Preiss, 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 (5 min)

**10:45 am**  
**Sponsor Presentation (45 Min)**
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 Presentation (35 min)**
- Joohee Lee, M.D., Medical Officer, Clinical Review Branch 1, DVRPA, OVRR, CBER, FDA

**12:05 pm**  
Lunch (25 min)

**12:30 pm**  
Open Public Hearing (60 min)

**1:30 pm**  
Break (10 Min)

**1:40 pm**  
Q & A regarding Sponsor and FDA presentations (45 min)

**2:25 pm**  
Committee Discussion and Voting (120 min)

**4:45 pm**  
Meeting Adjourned