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.

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