FOOD AND DRUG ADMINISTRATION (FDA)  
Center for Biologics Evaluation and Research (CBER)  
161st Meeting of the Vaccines and Related Biological Products Advisory Committee  
Silver Spring, MD  
October 22, 2020

AGENDA

**Topic I:** To discuss, in general, the development, authorization and/or licensure of vaccines to prevent COVID-19  
**Note:** Committee members are participating via web-conference

<table>
<thead>
<tr>
<th>Time</th>
<th>Presentation/Presenter</th>
</tr>
</thead>
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| 10:00 AM | **Opening Remarks: Call to Order, Introduction of Committee**  
Arnold Monto, M.D.  
Temporary Chair, VRBPAC  
Professor of Epidemiology  
School of Public Health  
University of Michigan  
**Administrative Announcements, Roll Call, Conflict of Interest Statement**  
Prabhakara Atreya, Ph.D.  
DSAC Director/Designated Federal Officer  
CBER, FDA |
| 10:20 AM | **Development, Authorization & Licensure of Vaccines to Prevent COVID-19**  
Marion F. Gruber, Ph.D.  
Director  
Office of Vaccines Research & Review  
CBER, FDA |
| 10:35 AM | **Epidemiology, Virology, and Clinical Features of COVID-19**  
Cliff McDonald, M.D.  
Senior Advisor for Science and Integrity  
Division of Healthcare Quality Promotion  
Centers for Disease Control and Prevention |
| 10:55 AM | **COVID-19 Vaccine Development: The Role of the NIH**  
Hilary Marston, M.D., M.P.H.  
Medical Officer and Policy Advisor for Pandemic Preparedness  
National Institute of Allergies and Infectious Diseases (NIAID)  
National Institute of Health (NIH) |
<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Presenter</th>
</tr>
</thead>
</table>
| 11:15 AM | **COVID-19 Vaccine Development Portfolio**                                | Robert Johnson, Ph.D.  
Director  
Influenza and Emerging Infectious Diseases Division  
Biomedical Advanced Development Research Authority (BARDA)  
Office of the Assistant Secretary for Preparedness and Response (ASPR)  
Health and Human Services (HHS) |
| 11:35 AM | **Break** (10 minutes)                                                   |                                                                                               |
| 11:45 AM | **CDC plans for Vaccine Safety monitoring & evaluation during future EUA use and post-licensure** | Tom Shimabukuro, M.D., M.P.H., M.B.A.  
Deputy Director  
Immunization Safety Office  
Division of Healthcare Quality Promotion  
National Center for Emerging and Zoonotic Infectious Diseases  
Centers for Disease Control and Prevention |
|          | **CDC plans for Effectiveness monitoring & evaluation during future EUA use and post-licensure** | Stephanie Schrag, D.Phil.  
Epidemiology Team Lead  
Respiratory Diseases Branch/Division of Bacterial Diseases  
Centers for Disease Control and Prevention |
| 12:05 PM | **CBER plans for Monitoring COVID-19 Vaccine Safety and Effectiveness**   | Steven Anderson, Ph.D.  
Director  
Office of Biostatistics and Epidemiology  
CBER/FDA |
Medical Officer and Program Lead  
Division of Viral Diseases  
National Center for Influenza and National Respiratory Diseases  
Centers for Disease Control and Prevention |
| 12:45 PM | **Lunch Break** (30 min)                                                 |                                                                                               |
| 1:15 PM  | **COVID-19 Vaccine Confidence**                                           | Susan Winckler, R.Ph., Esq.  
CEO  
Reagan-Udall Foundation (RUF) |
|          | **Chris Wilks, Ph.D.**                                                   | Researcher  
RUF |
<table>
<thead>
<tr>
<th>Time</th>
<th>Agenda Item</th>
</tr>
</thead>
<tbody>
<tr>
<td>1:30 PM</td>
<td><strong>Licensure and Emergency Use Authorization of Vaccines to Prevent COVID-19: Chemistry, Manufacturing, and Controls (CMC) Considerations</strong></td>
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</tbody>
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|       | **Jerry Weir, Ph.D.**  
Division of Viral Products (DVP)  
Office of Vaccines Research and Review (OVRR)  
CBER, FDA  |
| 1:55 PM | **Licensure and Emergency Use Authorization of Vaccines to Prevent COVID-19: Clinical Considerations**  |
|       | **Doran Fink, M.D., Ph.D.**  
Deputy Director  
Division of Vaccines and Related Products Applications  
Office of Vaccines Research and Review (OVRR)  
CBER, FDA  |
| 2:35 PM | **Break** (10 Minutes)  |
| 2:45 PM | **Open Public Hearing** (90 minutes)  |
| 4:15 PM | **Committee Discussion and Recommendations**  |
| 6:45 PM | **Adjourn Meeting**  |