**FOOD AND DRUG ADMINISTRATION (FDA)**
**Center for Biologics Evaluation and Research (CBER)**
**175th Meeting of the Vaccines and Related Biological Products Advisory Committee**
**June 28, 2022**
**AGENDA**

**Topic: The committee will meet in open session to discuss whether and how the SARS-CoV-2 strain composition of COVID-19 vaccines should be modified**

| Time | Presentation/Presenter |
|---|---|
| **8:30 a.m.** | **Opening Remarks: Call to Order and Welcome (5 Min)**<br><br>Arnold Monto, M.D. Acting Chair, VRBPAC<br>Emeritus Professor of Public Health and Epidemiology, University of Michigan<br><br>**Administrative Announcements, Roll Call, Introduction of Committee, Conflict of Interest Statement (20 Min)**<br><br>Prabhakar Atreya, Ph.D. Acting Designated Federal Officer, VRBPAC and Director, Division Scientific Advisors and Consultants, CBER, FDA<br>Sussan Paydar, Ph.D. Alternate Designated Federal Officer, VRBPAC |
| **8:55 a.m.** | **FDA Introduction (20 Min)**<br><br>**Considerations for Whether and How the COVID-19 Vaccine Strain Composition Should be Modified (15 Min)**<br><br>• Peter Marks, M.D., Ph.D.<br>Center Director, CBER, FDA<br><br>• Q/A – 5 Min |
| **9:15 a.m.** | **CDC Presentations (60 Min)**<br><br>**Update on Current Epidemiology of the COVID-19 Pandemic and SARS-CoV-2 Variants (20 Min)**<br><br>• CDR. Heather Scobie, Ph.D. M.PH.<br>Deputy Team Lead, Surveillance and Analytics<br>Epidemiology Task Force<br>COVID-19 Emergency Response<br>Centers for Disease Control and Prevention (CDC)<br><br>• Q/A – 10 Min |

**FOOD AND DRUG ADMINISTRATION (FDA)**
**Center for Biologics Evaluation and Research (CBER)**
**175th Meeting of the Vaccines and Related Biological Products Advisory Committee**
**June 28, 2022**
**AGENDA**

| | |
|---|---|
| | **Update on the Effectiveness of COVID-19 Vaccines (20 Min)**<br><br>• Ruth Link-Gelles, PH.D.M.PH.<br>LCDR, U.S. Public Health Service<br>COVID-19 Vaccine Effectiveness Program Lead<br>Division of Viral Diseases, CDC<br><br>• Q/A – 10 Min |
| **10:15 a.m.** | **Modeling Future Epidemiology of the COVID-19 Pandemic (20 Min)**<br><br>• Justin T. Lessler, Ph.D.<br>Professor, Dept. of Epidemiology<br>University of North Carolina, Chapel Hill<br><br>• Q/A – 10 Min |
| **10:45 a.m.** | **Break (15 Min)** |
| **11:00 a.m.** | **<u>Sponsor Presentations on Clinical Data Regarding Variant Vaccines (60 Min)</u>**<br><br>• Dr. Stephen Hoge, M.D. (15 Min)<br>President, ModernaTX<br><br>• Q & A (5 Min)<br><br>• Dr. Kena Swanson, Ph.D. (15 Min)<br>Vice President, Viral Vaccines<br>Vaccine Research and Development<br>Pfizer, Inc.<br><br>• Q & A (5 Min)<br><br>• Dr. Gregory M. Glenn (15 Min)<br>President, Research and Development<br>Novavax Inc.<br><br>• Q & A (5 Min) |

**FOOD AND DRUG ADMINISTRATION (FDA)**
**Center for Biologics Evaluation and Research (CBER)**
**175th Meeting of the Vaccines and Related Biological Products Advisory Committee**
**June 28, 2022**
**AGENDA**

| | |
|---|---|
| **12:00 p.m.** | **<u>WHO Presentation (25 Min)</u>**<br><br>**Considerations for Vaccine Strain Composition from the WHO TAG-Co-VAC (20 Min)**<br><br>• Kanta Subbarao, M.D. M.PH. (20 Min)<br>Director, WHO Collaborating Center for Reference and Research on Influenza, Peter Doherty Institute for Infection and Immunity, Melbourne, Australia<br><br>• Q/A - 5 Min |
| **12:25 p.m.** | **<u>FDA Presentation (35 Min)</u>**<br><br>**FDA Assessment of Available Data for Modified COVID-19 Vaccine Candidates and Consideration of Potential Changes to COVID-19 Vaccine Strain Composition (25 Min)**<br><br>• Jerry Weir, Ph.D.<br>Director, Division of Viral Products<br>Office of Vaccines Research and Review, CBER, FDA<br><br>• Q/A - 10 Min |
| **1:00 p.m.** | **Lunch (30 Min)** |
| **1:30 p.m.** | **Open Public Hearing (60 Min)** |
| **2:30 p.m.** | **Break (10 Min)** |
| **2:40 p.m.** | **Committee Discussion of Questions (100 Min)** |
| **4:20 p.m.** | **Voting and Vote explanation– (40 Min)** |
| **5:00 p.m.** | **<u>Meeting Adjourned - DFO</u>** |