**FOOD AND DRUG ADMINISTRATION (FDA)**  
Center for Biologics Evaluation and Research (CBER)  
173rd Meeting of the Vaccines and Related Biological Products  
Advisory Committee  
June 7, 2022  
DRAFT AGENDA

Topic: Emergency Use Authorization (EUA) request by Novavax for a vaccine to prevent COVID-19 in individuals 18 years of age and older

<table>
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<tr>
<th>Time</th>
<th>Presentation/Presenter</th>
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| 8:30 a.m. | **Opening Remarks: Call to Order and Welcome (5 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 |
| 8:55 a.m. | **FDA Introduction (20 min including Q &A)**  
Welcome (5 Min)  
• Peter Marks, M.D. Ph.D. Center Director, CBER, FDA  
Emergency Use Authorization (EUA) request by Novavax for a vaccine to prevent COVID-19 in individuals 18 years of age and older (10 Min)  
• Goutam Sen, Ph.D.  
Review Committee Chair  
Division of Vaccines and Related Product Applications (DVRPA)  
Office of Vaccines Research and Review (OVRR)  
CBER, FDA  
• Q/A - 5 Min |
| 9:15 a.m. | **CDC Presentations TBD (45 Min including Q &A)**  
Current Epidemiology of COVID-19 and COVID-19 Vaccination Rates in the United States (20 Min)  
• CDR. Heather Scobie, Ph.D. M.PH.  
Deputy Team Lead, Surveillance and Analytics Epidemiology Task Force  
COVID-19 Emergency Response  
Centers for Disease Control and Prevention (CDC)  
• Q/A - 5 Min  
Overview of COVID-19 Vaccine Associated Myocarditis (15 Min) |
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- CAPT. Tom Shimabukuro, M.D. M.PH. M.B.A.  
  Director, Immunization Safety Office  
  Centers for Disease Control and Prevention (CDC)

- Q/A – 5 Min

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<tr>
<td>10:00 a.m.</td>
<td><strong>Sponsor Presentation (60 Min including Q&amp;A)</strong></td>
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<td>Emergency Use Authorization (EUA) request by Novavax for a vaccine to prevent COVID-19 in individuals 18 years of age and older (50 min)</td>
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<tr>
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<td><strong>Emergency Use Authorization (EUA) Application for NVX-CoV2373</strong></td>
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<tr>
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<td><strong>Introduction</strong></td>
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</table>
|         | Filip Dubovsky, MD, MPH, FAAP  
  Executive Vice President & Chief Medical Officer, Novavax, Inc.  |
|         | **Immunogenicity and Efficacy**  |
|         | Raburn Mallory, MD  
  Senior Vice President & Head of Clinical Development, Novavax, Inc.  |
|         | **Safety**  |
|         | Denny Kim, MD, MPH  
  Senior Vice President & Chief Safety Officer, Head of Global Vaccine Safety, Novavax, Inc.  |
|         | **Clinical Perspective**  |
|         | Gregory A. Poland, MD, FIDSA, MACP, FRCP  
  Mary Lowell Leary Emeritus Professor of Medicine  
  Distinguished Investigator of the Mayo Clinic  
  Director, Mayo Vaccine Research Group  |
|         | **Conclusion**  |
|         | Filip Dubovsky, MD, MPH, FAAP  
  Executive Vice President & Chief Medical Officer, Novavax, Inc.  |

- Q &A – 10 Min

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<tr>
<td>11:00 a.m.</td>
<td><strong>Break (15 min)</strong></td>
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<td>11:15 a.m.</td>
<td><strong>FDA Presentations (60 min including Q&amp;A)</strong></td>
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<td>FDA Review of Effectiveness and Safety of Novavax COVID-19 Vaccine in individuals 18 years of age and older (50 min)</td>
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- Lucia Lee, MD
  Lead Medical Officer, Clinical Review Branch 1
  Division of Vaccines and Related Product Applications (DVRPA)
  Office of Vaccines Research and Review (OVRR), CBER, FDA
- Q/A – 10 Min

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<tr>
<td>12:15 p.m.</td>
<td>Lunch (45 min)</td>
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<tr>
<td>1:00 p.m.</td>
<td>Open Public Hearing (60 Min)</td>
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<tr>
<td>2:00 p.m.</td>
<td>Break (10 Min)</td>
</tr>
<tr>
<td>2:10 p.m.</td>
<td>Additional Q &amp; A regarding Sponsor and FDA presentations (50 Min)</td>
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<tr>
<td>3:00 p.m.</td>
<td>Committee Discussion and Voting (120 Min)</td>
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<td>5:00 p.m.</td>
<td>Meeting Adjourned – DFO</td>
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