

**FOOD AND DRUG ADMINISTRATION (FDA)  
Center for Biologics Evaluation and Research (CBER)  
173<sup>rd</sup> 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**

<b>Time</b>	<b>Presentation/Presenter</b>
<b>8:30 a.m.</b>	<p><b><u>Opening Remarks: Call to Order and Welcome (5 min)</u></b></p> <p>Arnold Monto, M.D. Acting Chair, VRBPAC Professor of Public Health and Epidemiology, University of Michigan</p> <p><b><u>Administrative Announcements, Roll Call, Introduction of Committee, Conflict of Interest Statement (20 min)</u></b></p> <p>Prabhakara Atreya, Ph.D. Acting Designated Federal Officer, VRBPAC Director, Division Scientific Advisors and Consultants, CBER, FDA</p>
<b>8:55 a.m.</b>	<p><b><u>FDA Introduction (20 min including Q &amp;A)</u></b></p> <p><b>Welcome (5 Min)</b></p> <ul style="list-style-type: none"> <li>• Peter Marks, M.D. Ph.D. Center Director, CBER, FDA</li> </ul> <p><b>Emergency Use Authorization (EUA) request by Novavax for a vaccine to prevent COVID-19 in individuals 18 years of age and older (10 Min)</b></p> <ul style="list-style-type: none"> <li>• Goutam Sen, Ph.D. Review Committee Chair Division of Vaccines and Related Product Applications (DVRPA) Office of Vaccines Research and Review (OVRR) CBER, FDA</li> <li>• Q/A - 5 Min</li> </ul>
<b>9:15 a.m.</b>	<p><b><u>CDC Presentations TBD (45 Min including Q &amp;A)</u></b></p> <p><b>Current Epidemiology of COVID-19 and COVID-19 Vaccination Rates in the United States (20 Min)</b></p> <ul style="list-style-type: none"> <li>• 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)</li> <li>• Q/A - 5 Min</li> </ul> <p><b>Overview of COVID-19 Vaccine Associated Myocarditis (15 Min)</b></p>

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	<ul style="list-style-type: none"> <li>• CAPT. Tom Shimabukuro, M.D. M.PH. M.B.A. Director, Immunization Safety Office Centers for Disease Control and Prevention (CDC)</li> <li>• Q/A – 5 Min</li> </ul>
<b>10:00 a.m.</b>	<p><b><u>Sponsor Presentation (60 Min including Q&amp;A)</u></b></p> <p><b>Emergency Use Authorization (EUA) request by Novavax for a vaccine to prevent COVID-19 in individuals 18 years of age and older (50 min)</b></p> <p><b>Emergency Use Authorization (EUA) Application for NVX-CoV2373 Introduction</b>  Filip Dubovsky, MD, MPH, FAAP  Executive Vice President &amp; Chief Medical Officer, Novavax, Inc.</p> <p><b>Immunogenicity and Efficacy</b>  Raburn Mallory, MD  Senior Vice President &amp; Head of Clinical Development, Novavax, Inc.</p> <p><b>Safety</b>  Denny Kim, MD, MPH  Senior Vice President &amp; Chief Safety Officer, Head of Global Vaccine Safety, Novavax, Inc.</p> <p><b>Clinical Perspective</b>  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</p> <p><b>Conclusion</b>  Filip Dubovsky, MD, MPH, FAAP  Executive Vice President &amp; Chief Medical Officer, Novavax, Inc.</p> <ul style="list-style-type: none"> <li>• Q &amp;A – 10 Min</li> </ul>
<b>11:00 a.m.</b>	<b>Break (15 min)</b>
<b>11:15 a.m.</b>	<p><b><u>FDA Presentations (60 min including Q&amp;A)</u></b></p> <p><b>FDA Review of Effectiveness and Safety of Novavax COVID-19 Vaccine in individuals 18 years of age and older (50 min)</b></p>

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	<ul style="list-style-type: none"> <li>• Lucia Lee, MD Lead Medical Officer, Clinical Review Branch 1 Division of Vaccines and Related Product Applications (DVRPA) Office of Vaccines Research and Review (OVRP), CBER, FDA</li> <li>• Q/A – 10 Min</li> </ul>
12:15 p.m.	<b><u>Lunch (45 min)</u></b>
1:00 p.m.	<b><u>Open Public Hearing (60 Min)</u></b>
2:00 p.m.	<b><u>Break (10 Min)</u></b>
2:10 p.m.	<b><u>Additional Q &amp; A regarding Sponsor and FDA presentations (50 Min)</u></b>
3:00 p.m.	<b><u>Committee Discussion and Voting (120 Min)</u></b>
5:00 p.m.	<b><u>Meeting Adjourned – DFO</u></b>