

**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

Time	Presentation/Presenter
8:30 a.m.	<p><u>Opening Remarks: Call to Order and Welcome (10 min)</u></p> <p>Arnold Monto, M.D. Acting Chair, VRBPAC Emeritus Professor of Public Health and Epidemiology, University of Michigan</p> <p><u>Administrative Announcements, Roll Call, Introduction of Committee, Conflict of Interest Statement (20 min)</u></p> <p>Prabhakara Atreya, Ph.D. Acting Designated Federal Officer, VRBPAC Director, Division Scientific Advisors and Consultants, CBER, FDA</p>
9:00 a.m.	<p><u>FDA Introduction (30 min including Q &A)</u></p> <p>Welcome (5 Min)</p> <ul style="list-style-type: none"> • Peter Marks, M.D. Ph.D. Center Director, CBER, FDA <p>Emergency Use Authorization (EUA) request by Novavax for a vaccine to prevent COVID-19 in individuals 18 years of age and older (10 Min)</p> <ul style="list-style-type: none"> • Goutam Sen, Ph.D. Review Committee Chair Division of Vaccines and Related Product Applications (DVRPA) Office of Vaccines Research and Review (OVRR) CBER, FDA
9:15 a.m.	<p><u>CDC Presentations TBD (45 Min including Q &A)</u></p> <p>Current Epidemiology of COVID-19 and COVID-19 Vaccination Rates in the United States (20 Min)</p> <ul style="list-style-type: none"> • 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 <p>Overview of COVID-19 Vaccine Associated Myocarditis (15 Min)</p> <ul style="list-style-type: none"> • CAPT. Tom Shimabukuro, M.D. M.PH. M.B.A.

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	<p>Director, Immunization Safety Office Centers for Disease Control and Prevention (CDC)</p> <ul style="list-style-type: none"> • Q/A – 5 Min
10:00 a.m.	<p><u>Sponsor Presentation (60 Min including Q&A)</u></p> <p>Emergency Use Authorization (EUA) request by Novavax for a vaccine to prevent COVID-19 in individuals 18 years of age and older (50 min)</p> <p>Emergency Use Authorization (EUA) Application for NVX-CoV2373 Introduction Filip Dubovsky, M.D., M.PH., FAAP Executive Vice President & Chief Medical Officer, Novavax, Inc.</p> <p>Immunogenicity and Efficacy Raburn Mallory, M.D. Senior Vice President & Head of Clinical Development, Novavax, Inc.</p> <p>Safety Denny Kim, M.D., M.PH. Senior Vice President & Chief Safety Officer, Head of Global Vaccine Safety, Novavax, Inc.</p> <p>Clinical Perspective Gregory A. Poland, M.D., FIDSA, MACP, FRCP Mary Lowell Leary Emeritus Professor of Medicine Distinguished Investigator of the Mayo Clinic Director, Mayo Vaccine Research Group</p> <p>Conclusion Filip Dubovsky, M.D., M.PH., FAAP Executive Vice President & Chief Medical Officer, Novavax, Inc.</p> <ul style="list-style-type: none"> • Q &A – 10 Min
11:00 a.m.	Break
11:15 a.m.	<p><u>FDA Presentations (60 min including Q&A)</u></p> <p>FDA Review of Effectiveness and Safety of Novavax COVID-19 Vaccine in individuals 18 years of age and older (50 min)</p> <ul style="list-style-type: none"> • Lucia Lee, M.D. Lead Medical Officer, Clinical Review Branch 1

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