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.	**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)**

	• 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
10:00 a.m.	**<u>Sponsor Presentation (60 Min including Q&A)</u>** **Emergency Use Authorization (EUA) request by Novavax for a vaccine to prevent COVID-19 in individuals 18 years of age and older (50 min)** **Emergency Use Authorization (EUA) Application for NVX-CoV2373 Introduction** 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
11:00 a.m.	**Break (15 min)**
11:15 a.m.	**<u>FDA Presentations (60 min including Q&A)</u>** **FDA Review of Effectiveness and Safety of Novavax COVID-19 Vaccine in individuals 18 years of age and older (50 min)**

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