#### FOOD AND DRUG ADMINISTRATION (FDA)

### Center for Biologics Evaluation and Research (CBER) 171<sup>st</sup> Meeting of the Vaccines and Related Biological Products Advisory Committee April 6, 2022 DRAFT AGENDA

Topic: The committee will meet in open session to discuss considerations for COVID-19 vaccine booster doses and the process for COVID-19 vaccine strain selection to address current and emerging variants

| Time      | Presentation/Presenter  |
|-----------|---|
| 8:30 a.m. | Opening Remarks: Call to Order and Welcome (10 min)   |
|           | Arnold Monto, M.D. Acting Chair, VRBPAC Emeritus 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  |
| 9:00 a.m. | FDA Introduction (15 min)   |
|           | Welcome (5 min)   |
|           | Peter Marks, M.D. Ph.D. Center Director, CBER, FDA  |
|           | Introduction to the Topic: COVID-19 vaccine booster vaccination (10 min)  |
|           | Doran Fink, M.D., Ph.D.     Deputy Director- Clinical     Division of Vaccines and Related Product Applications (DVRPA)     Office of Vaccines Research and Review (OVRR), CBER, FDA                      |
| 9:15 a.m. | Update on the Epidemiology of COVID-19 Variants (35 min)  |
|           | CDR Heather Scobie, PhD, M.PH. (30 min)     Deputy Team Lead, Surveillance and Analytics     Epidemiology Task Force     COVID-19 Emergency Response     Centers for Disease Control and Prevention (CDC) |
|           | • Q/A – 5 min   |
| 9:50 a.m. | COVID-19 Vaccine Effectiveness in Children and Adults (25 min)  |
|           | LCDR Ruth Link-Gelles, PhD, M.PH. (20 min)     Program Lead, COVID-19 Vaccine Effectiveness     Epidemiology Task Force     COVID-19 Emergency Response   |

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|            | Centers for Disease Control and Prevention (CDC)   |
|            | • Q/A – 5 min  |
| 10:20 a.m. | Israeli Experience with Fourth Booster Doses in Older Adults (20 min)  |
|            | <ul> <li>Sharon Alroy-Preis, M.D. M.PH.M.B.A – (10 min)</li> <li>Director, Public Health Services Ministry of Health, Jerusalem, Israel</li> </ul>   |
|            | Ron Milo. Ph.D (5 Min) Professor, Dept. of Plant and Environmental Sciences, Dean of Education, Weissman Institute, Rehovot, Israel  |
|            | Q/A – 5 min  |
| 10:40 a.m. | Break (10 min)   |
| 10:50 a.m. | Predicting Future SARS-CoV-2 Variants (30 min)   |
|            | John Beigel, M.D. (10 min)     Associate Director for Clinical Research     Division of Microbiology and Infectious Diseases     Office of the Director, NIAID, NIH  |
|            | <ul> <li>Trevor Bedford, Ph.D. (10 Min)     Professor, Fred Hutchinson Cancer Research Center     Investigator, Howard Hughes Medical Inst.     Seattle, WA</li> </ul>   |
|            | • Q &A – 10 Min  |
| 11:20 a.m. | Modeling of Future U.S. COVID-19 Outbreaks (30 min)  |
|            | Christopher Murray, M.D. D.Phil. (15 Min)     Professor and Chair     Department of Health Metrics Sciences     Director, Institute for Health Metrics and Evaluation (IHME)   |
|            | <ul> <li>Ali H. Mokdad, Ph.D. (5 min)     Professor, Health Metrics Sciences     Chief Strategy Officer, Population Health     Institute for Health Metrics and Evaluation (IHME)     School of Medicine, Washington University</li> </ul> |
|            | • Q &A – 10 Min  |

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| 11:50 a.m. | WHO Perspective on Variants for COVID-19 Vaccine Composition (20 min)  |
|------------|--|
|            | <ul> <li>Kanta Subbarao, M.D. M.PH. (15 min)         Director, WHO Collaborating Center for Reference and Research on Influenza, Peter Doherty Institute for Infection and Immunity Melbourne, Australia     </li> <li>Q &amp;A – 5 min</li> </ul> |
| 12:10 p.m. | Perspective on Variant Vaccine Development and Production (20 min)   |
|            | Robert Johnson, Ph.D. (15 min)     Deputy Assistant Secretary     Director, Medical Countermeasure Programs     Biomedical Advanced Research and Development Authority (BARDA)   |
| 40.20      | • Q &A – 5 min   |
| 12:30 p.m. | Proposed Framework for Addressing Future COVID-19 Outbreaks (30 min)  Jerry Weir, Ph.D. (20 min) Director, Division of Viral Products Office of Vaccines Research and Review (OVRR), CBER, FDA  Q/A – 10 min                                       |
| 1:00 p.m.  | Lunch (30 min)   |
| 1:30 p.m.  | Open Public Hearing (60 min)   |
| 2:30 p.m.  | Committee Discussion of Questions (150 min)  |
| 5:00 p.m.  | Meeting Adjourned  |