

**FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)**

Friday, March 4, 2016

**142nd Meeting of the Vaccines and Related Biological Products
Advisory Committee
FDA White Oak Campus, Building 31, Great Room (Room 1503)
Silver Spring, MD 20993**

Live Webcast: <https://collaboration.fda.gov/vrbpac030416/>.

AGENDA

| Time | Presentation/Presenter |
|-------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 8: 30 A.M. | Call to Order and Opening Remarks Introduction of Committee Ruth Lynfield, M.D. Acting Chair, VRBPAC |
| | Conflict of Interest Statement Sujata Vijn, Ph.D. Designated Federal Officer, VRBPAC, FDA |
| | Topic: Strain Selection for the Influenza Virus Vaccines for the 2016-2017 Influenza Season |
| 8:45a.m. | Introduction Anissa Cheung, M.Sc. Regulatory Coordinator Division of Viral Products Office of Vaccines Research and Review CBER/FDA |
| 8:55 a.m. | U.S. Surveillance Lisa Grohskopf, M. D., M. P. H. CAPT. USPHS Associate Chief for Policy & Liaison Activities, Epidemiology & Prevention Branch, Influenza Division Centers for Disease Control and Prevention |
| 9:20 a.m. | World Surveillance/ Virus Characterization Jacqueline Katz, Ph.D. Deputy Director (Acting), Influenza Division Director, WHO Collaborating Center for Surveillance, Epidemiology and Control of Influenza, Center for Immunization & Influenza, Center for Immunization & Respiratory Diseases Centers for Disease Control and Prevention |
| 10:20 a.m. | BREAK |

| Time | Presentation/Presenter |
|-------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 10:35 a.m. | DoD Vaccine Effectiveness Report Michael Cooper, Ph.D. CAPT, PHS Leader, Respiratory Pillar Activities Division of Global Emerging Infection Surveillance Armed Forces Health Surveillance Center |
| 10:55 a.m. | Vaccine Responses Zhiping Ye, M.D., Ph.D. Senior Investigator Division of Viral Products Office of Vaccines Research and Review CBER/FDA |
| 11:15 a.m. | Candidate Vaccine Strains & Potency Reagents Manju Joshi, Ph.D. Lead Biologist Division of Biological Standards & Quality Office of Compliance and Biologics Quality CBER/FDA |
| 11:35 a.m. | Comments from Manufacturers Matthew Downham, Ph.D. Associate Director, Biopharmaceutical Development AstraZeneca/MedImmune |
| 11:55 a.m. | LUNCH |
| 12:50 p.m. | Open Public Hearing |
| 1:50 p.m. | Committee Discussion, Voting and Recommendations |
| 3:00 p.m. | Adjournment |