FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
155th Meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC)
FDA White Oak Campus, Building 31, Great Room Salon B & C
Silver Spring, MD
March 6 & 7, 2019
AGENDA
Meeting Link:
https://collaboration.fda.gov/vrbpac032019/

Day 1 – March 6, 2019

Topic I: Strain Selection for the Influenza Virus Vaccines for the 2019 – 2020 Influenza Season
Topic II: Presentation of the Laboratory of Retroviruses (LR) and Laboratory of Immunoregulation (LIR), Division of Viral Products (DVP), Office of Vaccine Research and Review (OVRR), Center for Biologics Evaluation and Research (CBER)
Note: Committee members are participating in person

Time	Presentation/Presenter
8:00 AM	**Opening Remarks: Call to Order, Introduction of Committee** **Hana El Sahly, M.D.** Acting Chair, VRBPAC **Administrative Announcements, Conflict of Interest Statement** **Serina Hunter-Thomas, M.S.A., R.N.** Designated Federal Officer, VRBPAC CBER, FDA
8:15 AM	**Introduction** Anissa Cheung, M.Sc. Regulatory Coordinator Division of Viral Products Office of Vaccines Research and Review CBER/FDA
8:25 AM	**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 (CDC)
8:50 AM	**World Surveillance/Virus Characterization** Jacqueline Katz, Ph.D. Deputy Director, Influenza Division and Director, WHO Collaborating Center for Surveillance, Epidemiology and Control of Influenza National Center for Immunization and Respiratory Diseases Centers for Disease Control and Prevention (CDC)

9:55 AM	**DoD Vaccine Effectiveness Report** CDR Mark Scheckelhoff, Ph.D., M.P.H. Respiratory Pillar Chief Global Emerging Infections Surveillance Section Armed Forces Health Surveillance Branch Public Health Division Defense Health Agency
10:30 AM	**Candidate Vaccine Strains & Potency Reagents** Manju Joshi, Ph.D. Lead Biologist Division of Biological Standards & Quality Office of Compliance and Biologics Quality CBER/FDA
10:50 AM	**Comments from Manufacturers** Leslie Sands, M.S., R.A.C. Director, Global Regulatory Affairs Slaoui Center for Vaccine Research GlaxoSmithKline – Region US
11:10 AM	**Open Public Hearing** (45 min.)
11:55 AM	**Lunch** (45 min.)
12:40 PM	**Thank you – Dr. Kathryn Edwards** (15 min.)
12:55 PM	**Committee Discussion, Recommendations, and Vote**
2:00 PM	**Topic II: Presentation of the Laboratory of Retroviruses (LR) and Laboratory of Immunoregulation (LIR), Division of Viral Products (DVP), Office of Vaccine Research and Review (OVRR), Center for Biologics Evaluation and Research (CBER)**
2:05 PM	**Conflict of Interest Statement** Serina Hunter-Thomas Designated Federal Officer VRBPAC
2:10 PM	**Overview of Research/Site Visit Process, CBER** (15 min.) Carolyn Wilson, Ph.D. Associate Director for Research CBER/FDA

2:25 PM	**<u>Overview of Division of Viral Products (DVP)</u>** (15 min.) Jerry Weir, Ph.D. Director, Division of Viral Products Office of Vaccines Research and Review
2:40 PM	**<u>Overview of Laboratory of Immunoregulation (LIR)</u>** (15 min.) Carol Weiss, M.D, Ph.D. Principal Investigator
2:55 PM	**<u>Overview of Laboratory of Retroviruses (LR)</u>** (15 min.) Hana Golding, Ph.D. Principal Investigator
3:10 PM	**Open Public Hearing** (15 min.)
3:25 PM	**Closed Session**
3:30 PM	**Conflict of Interest Statement** Serina Hunter-Thomas Designated Federal Officer VRBPAC
3:35 PM	**<u>Committee Discussion, Recommendations and Vote</u>**
4:30 PM	**Adjourn Meeting**

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Day 2 – March 7, 2019

Topic III: Discuss and make recommendations on the safety and effectiveness of Dengue Tetravalent Vaccine (Live, Attenuated) [Dengvaxia] manufactured by Sanofi Pasteur.
Note: Committee members are participating in person

Time	Presentation/Presenter
8:30 AM	**Opening Remarks: Call to Order, Introduction of Committee** **Hana El Sahly, M.D.** Acting Chair, VRBPAC **Administrative Announcements, Conflict of Interest Statement** **Serina Hunter-Thomas, M.S.A., R.N.** Designated Federal Officer, VRBPAC CBER, FDA
8:45 AM	**Introduction and Presentation of Questions** **Kirk Prutzman, Ph.D.** Division of Vaccines and Related Product Applications (DVRPA) Office of Vaccines Research and Review (OVRR) Center for Biologics Evaluation and Research (CBER) Food and Drug Administration (FDA)
9:00 AM	**Epidemiology of Dengue** **Gabriella Paz-Bailey, M.D., M.Sc., Ph.D.** Centers for Disease Control and Prevention (CDC) Dengue Branch
9:45 AM	**Clinical Considerations of Dengue** **Anna Durbin, M.D.** John Hopkins University
10:30 AM	**Break** (15 minutes)

10:45 AM	**Sponsor Presentation** (90 minutes)
12:15 PM	**Lunch**
1:15 PM	**Open Public Hearing**
2:15 PM	**FDA Presentation** **Ralph LeBlanc, M.D., M.P.H.** Medical Officer DVRPA, CBER, FDA
2:45 PM	**Committee Discussion, Recommendations and Vote**
4:45 PM	**Adjourn Meeting**