FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
Meeting of the Vaccines and Related Biological Products Advisory Committee
FDA White Oak Campus, Building 31, Great Room
Silver Spring, MD
AGENDA
May 17, 2017

Meeting Link:
https://collaboration.fda.gov/rsvvaccine0517

Topic: The VRBPAC will meet in an open session to discuss considerations for clinical evaluation of Respiratory Syncytial Virus (RSV) vaccine candidates in seronegative infants.

Time	Presentation/ Presenter
8:30 – 8:45 a.m. (Note: All times are ET.)	**Opening Remarks: Call to Order, Introduction of Committee** **Kathryn Edwards, M.D.** Chair, VRBPAC **Administrative Announcements, Conflict of Interest Statement** **Serina Hunter-Thomas, M.S.A., R.N.** Designated Federal Officer, VRBPAC
8:45 – 9:00 a.m.	**Introduction of Presentation and Questions** **Jeff Roberts, M.D.** Medical Officer FDA/CBER/Office of Vaccines Research and Review (OVRR)
9:00 – 9:30 a.m.	**RSV Epidemiology** **Susan Gerber, M.D.** Chief (Acting), Respiratory Viruses Branch Centers for Disease Control/Division of Viral Diseases
9:30 – 10:30 a.m.	**History of Vaccine-Associated Enhanced Respiratory Syncytial Virus Disease and Characterization of Animal Models Designed to Mitigate Risk in Future Vaccine Studies** **Fernando Polack, M.D.** Scientific Director Fundacion INFANT
10:30 – 10:45 a.m.	**BREAK**
10:45 – 11:30 a.m.	**FDA Presentation** **Sarah Browne, M.D.** Medical Officer FDA/CBER/Office of Vaccines Research and Review (OVRR)

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11:30 – 12:00 p.m.	**GlaxoSmithKline Presentation** **Ilse Dieussaert** Director and Lead Vaccine Development, Maternal Immunization
12:00 – 1:15 p.m.	**LUNCH BREAK**
1:15 – 2:15 p.m.	**Open Public Hearing**
2:15 – 2:45 p.m.	**Janssen Vaccines and Prevention B.V. Presentation** **Roland Zahn, Ph.D.** Senior Scientific Director, Nonclinical **Melanie Saville, M.D.** Head of Late Development, Clinical and Medical Affairs, Vaccines
2:45 – 4:45 p.m.	**Committee Discussion**
4:45 p.m.	**Adjournment**