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.

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| 8:30 – 8:45 a.m. | 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) |

Agenda items are determined by the priorities of FDA and may change.
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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                                                                             |