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/rsrvaccine0517

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. (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) |

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                                                                                     |

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