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) |
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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                                                                              |