

**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 (Salon B&C)
Silver Spring, MD**

AGENDA

May 17, 2018

**Meeting
Link:**

<https://collaboration.fda.gov/vrbpac2018/>

Topic I: Approaches for demonstrating effectiveness of group B streptococcus (GBS) vaccines intended for use in pregnant women to protect the newborn infant **Topic II:** Presentation of the Laboratory of Respiratory Viral Diseases (LPRVD) Division of Viral Products (DVP), Office of Vaccines Research and Review (OVR), Center for Biologics Evaluation and Research (CBER)

Time	Presentation/Presenter
8:00 am	<p><u>Opening Remarks: Call to Order, Introduction of Committee</u></p> <p>Pamela McInnes, D.D.S., M.Sc. (Dent.) Acting Chair, VRBPAC</p> <p><u>Administrative Announcements, Conflict of Interest Statement</u></p> <p>Serina Hunter-Thomas, M.S.A., R.N. Designated Federal Officer, VRBPAC</p>
8:15 am	<p><u>Topic I: Approaches for demonstrating effectiveness of group B streptococcus (GBS) vaccines intended for use in pregnant women to protect the newborn infant</u></p> <p><u>FDA Introduction and Presentation of Questions</u> (15 min)</p> <p>Cara Fiore, Ph.D. Microbiologist Division of Vaccines and Related Products Applications (DVRPA) Office of Vaccines Research and Review (OVR), CBER</p>

<p>8:30 am</p>	<p>Evaluation of the Effectiveness of Vaccines Intended to Prevent Group B Streptococcal Disease in Infants (35 min)</p> <p>Darcie Everett, M.D., M.P.H. Clinical Reviewer Division of Vaccines and Related Products Applications (DVRPA) Office of Vaccines Research and Review (OVR), CBER</p>
<p>9:05 am</p>	<p>GBS Young Infant Disease Burden, Trends and Prevention Strategies: High Income Countries (30 min) Q & A (5 min)</p> <p>Stephanie Schrag, Ph.D. Epidemiology Team Lead Respiratory Diseases Branch Division of Bacterial Diseases Centers for Disease Control and Prevention Atlanta, GA</p>
<p>9:40 am</p>	<p>GBS Conjugate Vaccine: Early Development and Correlates of Protection (30 min) Q & A (5 min)</p> <p>Carol Baker, M.D. Professor of Pediatrics, Molecular Virology and Microbiology Baylor College of Medicine Houston, TX</p>
<p>10:15 am</p>	<p>Clinical and Immunological Epidemiology of GBS in Low-middle Income Settings (30 min) Q & A (5 min)</p> <p>Shabir Madhi, M.B.B.Ch., F.C.Paed, M.Med., Ph.D. Professor of Vaccinology, University of Witwatersrand Director, MRC Respiratory and Meningeal Pathogens Research Unit Chris Hani Baragwanath Hospital Gauteng, South Africa</p>
<p>10:50 am</p>	<p>The Burden of GBS Disease and Pfizer's GBS Vaccine (30 min) Q & A (5 min)</p> <p>Annaliesa Anderson, Ph.D., F.A.A.M. Vice President and Chief Scientific Officer Bacterial Research Vaccine Research and Development Unit Pfizer, Inc. Pearl River, NY</p>

	<p align="center">-and-</p> <p>Potential GBS Vaccine Clinical Development Pathways</p> <p>Judith Absalon, M.D., M.P.H. Senior Director, Global Clinical Program Lead (Group B Streptococcus Vaccine) Pfizer, Inc. Pearl River, NY</p>
11:25 am	Lunch (1 hour)
12:25 am	Open Public Hearing (45 min)
1:10 pm	Committee Discussion (90 min)
2:40 pm	Break (15 min)
2:55 pm	Topic II: Presentation of the Laboratory of Respiratory Viral Diseases (LPRVD) Division of Viral Products (DVP), Office of Vaccines Research and Review (OVR), Center for Biologics Evaluation and Research (CBER)
2:55 pm	<p>Conflict of Interest Statement (5 min)</p> <p>Serina Hunter-Thomas Designated Federal Officer VRBPAC</p>
3:00 pm	<p>Overview of Research/Site Visit Process, CBER (15 min)</p> <p>Carolyn Wilson, Ph.D. Associate Director for Research CBER/FDA</p>
3:15 pm	<p>Overview of DVP (15 min)</p> <p>Jerry Weir, Ph.D. Director, Division of Viral Products Office of Vaccines Research and Review CBER/FDA</p>
3:30 pm	<p>Overview of LRVD (15 min)</p> <p>Zhiping Ye, M.D., Ph.D. Principal Investigator/Lab Chief, DVP Office of Vaccines Research and Review CBER/FDA</p>

3:45 pm	Open Public Hearing (15 min)
4:00 pm	<u>Closed Session</u> (50 min)
4:05 pm	Conflict of Interest Statement (5 min) Serina Hunter-Thomas Designated Federal Officer VRBPAC
4:50 pm	Adjourn Meeting