

**FOOD AND DRUG ADMINISTRATION (FDA)  
Center for Biologics Evaluation and Research (CBER)  
November 13, 2015**

**140<sup>th</sup> Meeting of the Vaccines and Related Biological Products Advisory Committee  
FDA White Oak Campus, Building 31, Great Room (Room 1503)  
Silver Spring, MD**

Live Webcast: <https://collaboration.fda.gov/vrbpac1115/>

**DRAFT AGENDA**

**Topic: Considerations for evaluation of the safety and effectiveness of vaccines administered to pregnant women to protect the infant**

<b>Time</b>	<b>Presentation/ Presenter</b>
<b>8:45 A.M.</b>	<b>Call to Order and Opening Remarks</b> <b>Introduction of Committee</b> Robert Daum, M.D., Chair, VRBPAC  <b>Conflict of Interest Statement</b> Sujata Vijn, Ph.D. Designated Federal Officer VRBPAC, FDA
<b>8:55 a.m.</b>	<b>Introduction &amp; Presentation of Questions</b> Marion Gruber, Ph.D. Director, Office of Vaccines Research and Review (OVRR), CBER, FDA
<b>9:10 a.m.</b>	<b>NIH Presentation</b> Richard Gorman, M.D. Associate Director for Clinical Research DMID, National Institute of Allergy and Infectious Diseases (NIAID)
<b>9:40 a.m.</b>	<b>Bill and Melinda Gates</b> Ajoke Sobanjo-ter Meulen, M.D. Lead, Maternal Immunization Portfolio
<b>10:30 a.m.</b>	Break
<b>10:45 a.m.</b>	Open Public Hearing
<b>11:45 a.m.</b>	Lunch
<b>12:45 p.m.</b>	<b>Recognition of Retiring Members</b> Karen Midthun, M.D. Director, CBER, FDA
<b>1:00 p.m.</b>	<b>FDA Presentation</b> Jeff Roberts, M.D. Medical Officer Division of Vaccines and Related Product Applications (DVRPA) OVRR, FDA
<b>1:40 p.m.</b>	Break
<b>1:55 p.m.</b>	Committee Discussion
<b>4:00 p.m.</b>	Adjournment