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

September 13, 2017

Meeting Link:
https://collaboration.fda.gov/vrbpac0917/.

Topic: Discuss and make recommendations on the safety and effectiveness of Zoster Vaccine Recombinant (Adjuvanted) [Shingrix], manufactured by GlaxoSmithKline Biologicals.

Time	Presentation/Presenter
8:30 am	**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 am	**Introduction and Presentation of Questions** **Carmen Collazo-Custodio, Ph.D.** Microbiologist Division of Vaccines and Related Product Applications (DVRPA) Office of Vaccines Research and Review (OVRR), CBER
9:00 am	**Epidemiology and Disease Burden of Herpes Zoster in Adults aged 50 years and Older** **Jeffrey Cohen, M.D.** Chief, Laboratory of Infectious Diseases National Institute of Allergy and Infectious Diseases (NIAID) National Institutes of Health (NIH)

10:00 am	**Sponsor Presentations: GlaxoSmithKline** **Introduction: Kimber Poffenberger, Ph.D.** Vice President and Head North American Regulatory Affairs, GSK Vaccines **HZ Epidemiology and Burden of Disease: Barbara Yawn, M.D., M.Sc., F.A.A.F.P.** Adjunct Professor Department of Family and Community Health University of Minnesota, School of Medicine **Vaccine Design and Scientific Rationale**: **Arnaud Didierlaurent, Ph.D.** Director and Head of Adjuvant Platform, Belgium R&D, GSK Vaccines **HZ/su Clinical Efficacy Data** **HZ/su Immunogenicity**: **Jacqueline M. Miller, M.D., F.A.A.P.** Vice President and Head, US Clinical R&D, GSK Vaccines **HZ/su Safety**: **Jens-Ulrich Stegmann, R.N, M.D.** Vice President and Head Clinical Safety and Pharmacovigilance, GSK Vaccines **Conclusions**: **Jacqueline M. Miller, M.D., F.A.A.P.** Vice President and Head, US Clinical R&D, GSK Vaccines
11:30 am	**Lunch**
12:30 pm	**FDA Presentation: Paula Agger, M.D., M.P.H.** Medical Officer DVRPA, OVRR, CBER
1:30 pm	**Open Public Hearing**
2:30pm	**Committee Discussion and Vote**
4:00 pm	Adjourn Meeting