FOOD AND DRUG ADMINISTRATION (FDA)  
Center for Biologics Evaluation and Research (CBER)  
150th Meeting of the Vaccines and Related Biological Products Advisory Committee  
FDA White Oak Campus, Building 31, Great Room  
Silver Spring, MD  

November 7, 2017  

AGENDA  
Meeting Link:  
https://collaboration.fda.gov/cbervrbpac2017  

Topic: The committee will meet in an open session to discuss and make recommendations on the clinical development plan for Pfizer’s investigational *Staphylococcus aureus* vaccine intended for pre-surgical prophylaxis in elective surgical populations.

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| 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  
CBER, FDA |
| 8:45 am| **FDA Presentation: Clinical Development of Pfizer’s Investigational *Staphylococcus aureus* Vaccine for Prevention of Postoperative Infection in Elective Orthopedic Surgeries**  
Jeff Roberts, M.D.  
Chief, Clinical Review Branch 1  
Division of Vaccines and Related Product Applications (DVRPA)  
Office of Vaccines Research and Review (OVRR)  
Center for Biologics Evaluation and Research (CBER)  
Food and Drug Administration (FDA) |
| 9:00 am| **Scientific Considerations: Pathogenesis of *Staphylococcus aureus* Infection**  
Michael Otto, Ph.D., M.S.  
Chief, Pathogen Molecular Genetics Section  
National Institute of Allergy and Infectious Diseases (NIAID)  
National Institutes of Health (NIH) |
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| 9:45 am | **Clinical Considerations: Postoperative *Staphylococcal* Infection, Disease Manifestations, and Therapeutic Options**  
Richard Proctor, M.D.  
Professor Emeritus of Medical Microbiology and Immunology  
University of Wisconsin School of Medicine and Public Health  
Madison, Wisconsin |
| 10:30 am | Break |
| 10:45 am | **Sponsor Presentations:**  
**Orthopedic Infections: Challenging Problem**  
Javad Parvizi M.D., F.R.C.S.  
James Edwards Professor of Orthopaedic Surgery  
Sidney Kimmel School of Medicine  
Rothman Institute at Thomas Jefferson University  

**S. aureus Surgical site Infection (SSI) in Spinal Surgery**  
Thomas Errico, M.D.  
Professor of Orthopedic Surgery and Neurosurgery  
NYU School of Medicine  

**Proposed Plan and Rationale to Support a SA4Ag Indication in Elective Orthopedic Surgery**  
Bill Gruber, M.D., F.A.A.P., F.I.D.S.A.  
Senior Vice President  
Vaccine Clinical Research & Development  
Pfizer Inc. |
| 12:10 pm | Lunch |
| 1:10 pm  | Open Public Hearing |
| 2:10 pm  | **FDA Presentation: Considerations for Pfizer's Investigational *Staphylococcus aureus* Vaccine Intended for Pre-Surgical Prophylaxis in Elective Orthopedic Surgical Populations**  
Tina Mongeau, M.D., M.P.H.  
Medical Officer  
DVRPA, CBER, FDA |
| 2:40 pm  | Committee Discussion |
| 4:40 pm  | Adjourn Meeting |