

**FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
147th 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

July 28, 2017

**Meeting
Link:**

<https://collaboration.fda.gov/vrbpaco72817/>.

Topic: Safety and Efficacy of a Hepatitis B Vaccine manufactured by Dynavax

Time	Presentation/Presenter
8:30 am	<p>Opening Remarks: Call to Order, Introduction of Committee</p> <p>Kathryn Edwards, M.D. Chair, VRBPAC</p> <p>Administrative Announcements, Conflict of Interest Statement</p> <p>Serina Hunter-Thomas, M.S.A., R.N. Designated Federal Officer, VRBPAC</p>
8:45 am	<p>Introduction and Presentation of Questions</p> <p>Marian Major, PhD Chief, Laboratory of Hepatitis Viruses Division of Viral Products (DVP) Office of Vaccines Research and Review (OVR), CBER</p>
9:00 am	<p>Sponsor Presentations: Dynavax</p> <p>Introduction: Robert Janssen, MD CMO, Vice President of Clinical Development Dynavax Technologies Corporation</p>

Time	Presentation/Presenter
	<p>Unmet Public Health Need: William Schaffner, MD Professor of Preventive Medicine and Infectious Disease Vanderbilt University School of Medicine</p> <p>Mechanism of Action: Stanley Plotkin, MD Emeritus Professor, University of Pennsylvania and Member, Board of Directors Dynavax Technologies Corporation</p> <p>Immunogenicity and Safety: Robert Janssen, MD CMO, Vice President of Clinical Development Dynavax Technologies Corporation</p> <p>Cardiovascular Safety: Darren McGuire, MD Professor of Medicine University of Texas Southwestern Medical Center</p> <p>Proposed Post-Marketing Surveillance Study Robert Janssen, MD CMO, Vice President of Clinical Development Dynavax Technologies Corporation</p> <p>Benefit / Risk Conclusion: Gregory Poland, MD Professor of Medicine Mayo Clinic</p>
10:30 am	Break
10:45 am	<p>FDA Presentations</p> <p>Immunogenicity: Alexandra Worobec, MD Clinical Reviewer, Division of Vaccines and Other Related Product Applications (DVRPA), OVR, CBER</p> <p>Safety: Darcie Everett, MD, MPH Clinical Reviewer, (DVRPA), OVR, CBER</p>

Time	Presentation/Presenter
	<p>Statistical Analysis of Acute Myocardial Infarction Risk: John Scott, PhD Acting Director, Division of Biostatistics, Office of Biostatistics and Epidemiology (OBE), CBER</p>
12:15 pm	Lunch
1:15 pm	Open Public Hearing
2:15 pm	Committee Discussion and Vote
5:00 pm	Adjourn Meeting