Food and Drug Administration
Center for Biologics Evaluation and Research

SUMMARY MINUTES
143rd VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE MEETING

May 11, 2016

Committee Members
Kathryn Edwards, M.D., Chair
Janet Englund, M.D.
David Greenberg, M.D.#
Karen Kotloff, M.D.
Ofer Levy, M.D., Ph.D.
Sarah Long, M.D.
Ruth Lynfield, M.D.
Arnold Monto, M.D.
Patrick Moore, M.D., M.P.H.
Mark Sawyer, M.D.

Temporary Voting Member
Ellen Andrews, Ph.D. *

FDA Participants
Carolyn Wilson, Ph.D.
Marion Gruber, Ph.D.
Jay Slater, M.D.
Drusilla Burns, Ph.D.
William Vann, Ph.D.

Designated Federal Officer
Sujata Vijh, Ph.D.

Committee Management Specialist
Rosanna Harvey

Industry Representative
* Temporary Consumer Representative
(Consumer Representative Position is Vacant)

These summary minutes for the May 11, 2016 Meeting of the Vaccines and Related Biological Products Advisory Committee were approved on June 18, 2016.

I certify that I participated on the May 11, 2016 Meeting of the Vaccines and Related Biological Products Advisory Committee and that these minutes accurately reflect what transpired.

/S/	/S/
Sujata Vijh, Ph.D.	Kathryn Edwards, M.D.
Designated Federal Officer	Chair of VRBPAC

On May 11, 2016 at 1:00 p.m. Eastern Standard Time (EST), Dr. Kathryn Edwards, the Chair of VRBPAC, called to order the 143rd Meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC). The partially closed meeting was held at the Food and Drug Administration (FDA), 10903 New Hampshire Avenue, Building 31, White Oak Campus, Silver Spring, MD 20993. The open session of the meeting was open to members of the Public. VRBPAC members participated via teleconference for the open and closed sessions. The topic of the meeting was the February 4, 2016 site visit of the intramural research programs of the Laboratory of Bacterial Polysaccharides (LBP) in the Division of Bacterial, Parasitic, and Allergenic Products (DBPAP), Office of Vaccines Research and Review (OVRR), Center for Biologics Evaluation and Research (CBER).

After the meeting was called to order by the Dr. Edwards, the Designated Federal Officer (DFO) took a roll call of the VRBPAC members for the public record, followed by member introductions by Dr. Edwards. The DFO made administrative remarks and read the conflict of interest statement for the public record noting that the meeting topic was a non-particular matter meeting and that the committee discussion presented no potential for a conflict of interest.

Open Session

During the open session, the committee heard presentations of an overview of the CBER Research and Site Visit Process from Dr. Carolyn Wilson, CBER's Associate Director for Research. An overview of OVRR's research programs was provided by Dr. Marion Gruber followed by an overview of the DBPAP from its Director, Dr. Jay Slater. Dr. William Vann, the Chief of LBP, gave an overview of LBP's research program and the progress that was made since the previous site visit. The committee was given the opportunity to ask the presenters clarifying questions following which an Open Public Hearing session was announced. Since no public members were present and there was no public comment, the open session was adjourned at 1:46 p.m. and the meeting proceeded to the closed session.

Details of the open session may be obtained from the official transcript of the meeting that is available at http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/VaccinesandRelatedBiologicalProductsAdvisoryCommittee/ucm474746.htm