Food and Drug Administration
Center for Biologics Evaluation and Research

# SUMMARY MINUTES
# 154th VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

**November 8, 2018**

**Committee Members**
Kathryn Edwards, M.D.,Chair+
Hana El Sahly, M.D. ^
David Greenberg, M.D. +
Holly Janes, Ph.D. ^
Michael Kurilla, M.D., Ph.D. +
Myron Levine, M.D. ^
Ofer Levy, M.D., Ph.D. +
H. Cody Meissner, M.D. ^
Arnold Monto, M.D. *^
Paul Offit, M.D. ^
Andrea Shane, M.D., M.P.H., M.Sc. ^
Paul Spearman, M.D. +
Geeta Swamy, M.D. ^
Melinda Wharton, M.D., M.P.H. ^

**Designated Federal Officer (DFO)**
Serina A. Hunter-Thomas, M.S.A., R.N.

**Committee Management Specialist**
Joanne Lipkind, M.S.

**Consumer Representative**
Sheldon V. Toubman, J.D. ^

**Industry Representative (Alt.)**
Leonard Friedland, M.D. ^

**FDA Participants**
Carolyn Wilson, Ph.D.
Marion Gruber, Ph.D.
Konstantin Chumakov, Ph.D.
Robin Levis, Ph.D.

+ Not in attendance
* Acting VRBPAC Chair
^ Via Teleconference

These summary minutes for the November 8, 2018 Meeting of the Vaccines and Related Biological Products Advisory Committee were approved on December 13, 2018.

I certify that I participated in the November 8, 2018 Meeting of the Vaccines and Related Biological Products Advisory Committee and that these minutes accurately reflect what transpired.

/s/
Serina A. Hunter-Thomas
Designated Federal Officer

/s/
Arnold Monto, M.D.
Acting Chair

On November 8, 2018 at 11:00 a.m. Eastern Standard Time (EST), Dr. Arnold Monto, Acting VRBPAC Chair, called to order the 154th Meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) to discuss Topic I: Presentation of the Laboratory of DNA Viruses (LDV), Division of Viral Products (DVP), Office of Vaccine Research and Review (OVRR), Center for Biologics Evaluation and Research (CBER). The Acting Chair invited committee members to introduce themselves, followed by the DFO's administrative remarks and reading of the Conflict of Interest (COI) statement into the public record. After the COI statement was read by the DFO, the presentations began starting with Dr. Carolyn Wilson, who provided an overview of the Research/Site Visit Process in CBER. This was followed by an overview of the Division of Viral Products by Dr. Jerry Weir, and then an overview of the Laboratory of DNA Viruses by Dr. Keith Peden. Dr. Peden's presentation was followed by the Open Public Hearing (OPH) session portion of the meeting, however there were no speakers present to comment.

On November 8, 2018 at 12:05 p.m. Eastern Standard Time (EST), the Committee met in closed session which lasted until 2:00 p.m. Eastern Standard Time (EST).

The meeting was adjourned at 2:00 p.m. on November 8, 2018.

Additional information and details may be obtained from the transcript and the recording of the webcast of the meeting that may be viewed at:

https://collaboration.fda.gov/p6fagh24yysl/