

Food and Drug Administration  
Center for Biologics Evaluation and Review

SUMMARY MINUTES  
118<sup>th</sup> Meeting of the BLOOD PRODUCTS ADVISORY COMMITTEE  
White Oak Conference Center  
Great Room, Building 31  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

June 22, 2018

Committee Members

Meera B. Chitlur, M.D.+  
Alfred DeMaria, M.D. +  
Michael DeVan, M.D., F.C.A.P.,#  
Miguel Escobar, M.D.#  
Susan F. Leitman, M.D. +  
Roger Lewis, M.D., Ph.D., FACEP +  
Thomas Ortel, M.D., Ph.D.#  
Robert J. Rees, MHA, MT(ASCP) +  
Sonja Sandberg, SB., Ph.D.#  
Jack Stapleton, M.D. +

Temporary Voting Members

Suzette A. Priola, Ph.D. (Acting Chair) +  
Richard Kaufman, M.D.+  
Andrei Kindzelski, M.D., Ph.D.+  
Amy Shapiro, M.D.+  
Martin Schreiber, M.D.+

Industry Representative

Susan Stramer, Ph.D.+

Designated Federal Official

LCDR Bryan Emery M.A., B.S.N. USPHS

FDA Participants

Rachel Anatol, Ph.D.  
David Asher, M.D.  
C.D. Atreya, Ph.D.  
Wilson Bryan, M.D.  
Suzanne Epstein, Ph.D.  
Basil Golding, M.D.  
Indira Hewlett, Ph.D.  
Peyton Hobson, Ph.D.  
Gerardo Kaplan, Ph.D.  
Chava Kimchi-Sarfati, Ph.D.  
Timothy Lee, Ph.D.  
Peter Marks, M.D., Ph.D.  
Hira Nakhasi, Ph.D., FASTMH  
Mikhail Ovanesov, Ph.D.  
Zuben Sauna, Ph.D.  
Andrey Sarafanov, Ph.D.  
Nicole Verdun, M.D.  
Carolyn Wilson, Ph.D.

Consumer Representative

Judith Baker, DrPH, MHSA+

Committee Management Specialist

Joanne Lipkind, M.S.

These summary minutes for the June 22, 2018 meeting of the Blood Products Advisory Committee were approved on \_\_\_\_August 16, 2018\_\_\_\_.

# Did not attend

+ Attended by phone

I certify that I participated in the June 22, 2018 meeting of the Blood Products Advisory Committee via phone and that these minutes accurately reflect what transpired.

\_\_\_\_//Signed//\_\_\_\_  
Bryan Emery, LCDR  
Designated Federal Official

\_\_\_\_//Signed//\_\_\_\_  
Suzette A. Priola., Ph.D.  
Acting Chair

The Acting Chair, Dr. Suzette Priola, called the meeting of the Blood Products Advisory Committee (BPAC) to order at 11:00 a.m. EST on June 22, 2018. Members participated by phone and FDA personnel and members of the public participated in the Great Room. The open session of the meeting was also webcast. Introductions of the Blood Products Advisory Committee members, the Temporary Voting Members and FDA personnel were made. The DFO, LCDR Bryan Emery gave brief instructions and read into the official record the conflicts of interest statement pertaining to the meeting participants.

### QUICK SUMMARY

**Topic I: Review of the Research Programs in the Laboratories of Emerging Pathogens, Bacterial and Transmissible Spongiform Encephalopathy Agents, and Molecular Virology, Division of Emerging Transfusion-Transmitted Diseases (DETTD), Office of Blood Research and Review (OBRR), Center for Biologics Evaluation and Research (CBER)**

Before discussing the site visit report in the closed session, the Committee heard the following presentations:

- Overview of CBER Research Programs by Carolyn Wilson, Ph.D., CBER, FDA
- Overview of OBRR Research Programs by C.D. Atreya, Ph.D., OBRR, FDA
- Overview of the Division of Emerging Transfusion Transmitted Diseases Research Programs (DETTD) by Hira Nakhasi, Ph.D., OBRR, FDA

After the presentations were given, no questions were asked of the speakers.

An Open Public Hearing was announced. No one from the public requested to speak during the Open Public Hearing. No presentations were made during the Open Public Hearing.

A short break was taken to clear the room in order to begin the Closed Session Discussion.

The Committee then met in closed session to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy. The Committee discussed the site visit report of the DETTD laboratories and made recommendations regarding personnel staffing decisions.

The Committee reconvened after lunch and began Topic II in open session. The Acting Chair, Dr. Suzette Priola, began the afternoon session of the Blood Products Advisory Committee meeting with introductions of the Blood Products Advisory Committee members and Temporary Voting Members. Members participated by phone and FDA personnel and members of the public participated in the Great Room. The open session of the meeting was also webcast. Introductions of the Blood Products Advisory committee members, the Temporary Voting Members and FDA personnel were made. The DFO, LCDR Bryan Emery gave brief instructions to those in the public, on the phone and those around the table.

**Topic II: Review of the Research Program of the Hemostasis Branch (HB), Division of Plasma Protein Therapeutics (DPPT), Office of Tissues and Advanced Therapies (OTAT), Center for Biologics Evaluation and Research (CBER)**

Before discussing the site visit report in the closed session, the Committee heard the following presentations:

- Overview of OTAT Research Programs by Suzanne Epstein, Ph.D., OTAT, FDA
- Overview of DPPT Research Programs by Basil Golding, M.D., OTAT, FDA
- Overview of the Hemostasis Branch (HB) by Timothy Lee, Ph.D., OTAT, FDA

After the presentations were given, no questions were asked of the speakers.

An Open Public Hearing was announced to the room. No one from the public requested to speak during the Open Public Hearing before the meeting. No presentations were made by the public during the Open Public Hearing time.

A short break was taken to clear the room in order to begin the Closed Session Discussion.

The Committee then met in closed session to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy. The Committee discussed the site visit report of the research program of the Hemostasis Branch laboratory and made recommendations regarding personnel staffing decisions.

Acting Chair, Dr. Suzette Priola, adjourned the meeting at approximately 3:45 p.m.

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

<https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/BloodProductsAdvisoryCommittee/ucm554807.htm>