Food and Drug Administration
Center for Biologics Evaluation and Review

SUMMARY MINUTES
114th Meeting of the BLOOD PRODUCTS ADVISORY COMMITTEE

November 18, 2016
Great Room, Building 31
FDA White Oak Campus
10903 New Hampshire Avenue
Silver Spring, MD 20903

Committee Members
Sridhar Basavaraju, M.D., FACEP #
Meera B. Chitlur, M.D. #
Miguel Escobar, M.D.
John B. Holcomb, M.D., F.A.C.S. #
Susan F. Leitman, M.D. ##
Norma B. Lerner, M.D., M.P.H.
Thomas Ortel, M.D., Ph.D.
Margaret V. Ragni, M.D., M.P.H. #
Robert J. Rees, MHA, MT(ASCP)
Sonja Sandberg, SB., Ph.D.
Christopher Stowell, M.D., Ph.D. #

FDA Participants
Hira Nakhasi, Ph.D.
Jaro Vostal, M.D., Ph.D
Alan Williams, Ph.D.
Jay Epstein, M.D

Temporary Voting Members
Alfred DeMaria, M.D.
Michael DeVan, M.D., F.C.A.P., CDR MC USN
Jack Stapleton, M.D.

Guest Speaker
Lisa Pate, M.D., JD.
Ingrid Rabe, MBChB, Mmed
Reiner Ziermann, Ph.D.

Acting Industry Representative
Toby Simon, M.D.

Acting Consumer Representative
Christopher Templin

Designated Federal Official
LCDR Bryan Emery M.A., B.S.N. USPHS

Committee Management Specialists
Joanne Lipkind
Rosanna Harvey

Did not attend
Acting Chair

The summary minutes for the November18, 2016 Meeting of the Blood Products Advisory Committee were approved on October 18, 2016.

I certify that I participated in the November 18, 2016. Meeting of the Blood Products Advisory Committee and that these minutes accurately reflect what transpired.

/Signed/
Bryan Emery, LCDR
Designated Federal Official

/Signed/
Susan Leitman., M.D.
Acting Chair

QUICK SUMMARY

The Acting Chair, Dr. Susan Leitman, called the second day of the 114th Meeting of the Blood Products Advisory Committee (BPAC) to order at 8:30 a.m. EST on November 18, 2016. The meeting was held in an open session. The Acting Chair invited the members, temporary members, and participants seated at the table to introduce themselves. The Designated Federal Official (DFO) LCDR Bryan Emery made administrative remarks and read into the official record the Conflicts of Interest statement pertaining to the meeting participants. There were no waivers issued for conflicts of interest for this meeting. After the Conflicts of Interest statement was read for the public record by the DFO, the FDA and non-FDA speaker presentations began.

Topic III: Informational Session: Zika Virus and Blood Safety in the United States

In open session, the committee listened to an informational session on Zika virus and blood safety in the United States. Captain Ingrid Rabe of the Centers for Disease Control and Prevention presented on the current status of the Zika Virus epidemic. Dr. Hira Nakhasi of the FDA presented on FDA's recommendations to reduce the risk of transfusion-transmitted Zika virus and other efforts with respect to blood safety. Dr. Lisa Pate of Roche and Dr. Rainer Ziermann of Hologic also gave presentations on testing donations for Zika virus under investigation new drug (IND) applications in the United States.

Following the questions for the speakers, the Chair read the Open Public Hearing statement during the start of the Open Public Hearing session. Dr. Susan Stramer representing AABB, America's Blood Centers and the American Red Cross made a presentation during the Open Public Hearing. Several members of the committee made comments in response to the Open Public Hearing speaker during the Open Public Hearing. Last a prepared statement was read by Dr. Jay Epstein of the FDA regarding industry's concerns with FDA's recommendations.

Following the Open Public Hearing, the committee took a 15-minute break.

Committee Updates:

The committee reconvened in open session to listen to a committee update presentations. Dr. Alan Williams of the FDA presented an update on the Transfusion Transmissible Infections Monitoring System. To conclude the committee updates, Dr. Jaro Vostal of the FDA presented a summary of the FDA workshop on pre-clinical evaluation of red blood cells for transfusion.

An Open Public Hearing was announced after the Committee update presentation. There were no requests for presentations during the Open Public Hearing.

Dr. Susan Leitman, the Acting Chair, adjourned the meeting at approximately 12:00 p.m.

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://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/BloodProductsAdvisoryCommittee/ucm501664.htm