Food and Drug Administration
Center for Biologics Evaluation and Research

SUMMARY MINUTES
113th BLOOD PRODUCTS ADVISORY COMMITTEE MEETING

June 20, 2016

Committee Members
Susan Leitman, M.D., Acting Chair
Sridhar V. Basavaraju, M.D., FACEP
Meera B. Chitlur, M.D.
Mr. Corey Dubin** +
Valerie Durkalski-Mauldin, Ph.D., MPH
John Holcomb, M.D., F.A.C.S. +
Norma B. Lerner, M.D., MPH
Margaret Ragni, M.D., MPH
Sonja Sandberg, S.B., Ph.D. +
Robert J. Rees., MHA, MT (ASCP)
Katherine Schexneider, M.D., CDR MC, USN
Toby L. Simon, M.D. #
Christopher Stowell, M.D. Chair+

Temporary Voting Member
Francisco Bonilla, M.D.
Judith R. Baker, DPH., MHSA*

Designated Federal Officer
LCDR Bryan Emery, MA, BSN.

Committee Management Specialist
Joanne Lipkind

FDA Participants
Peter Marks, M.D., Ph.D.
Carolyn Wilson, Ph.D.
C.D. Atreya, Ph.D.
Basil Golding, M.D.
Dorothy Scott, M.D.

+ Not in attendance
# Industry Representative
* Temporary Consumer Representative
** Consumer Representative

These summary minutes for the June 20, 2016 Meeting of the Blood Products Advisory Committee were approved on August 4, 2016.

I certify that I participated on the June 20, 2016 Meeting of the Blood Products Advisory Committee and that these minutes accurately reflect what transpired.

_____/Signed/_____
LCDR Bryan Emery, MA, BSN
Designated Federal Officer

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

On June 20, 2016 at 9:30 a.m. Eastern Standard Time (EST), Dr. Susan Leitman, the Acting Chair of BPAC, called to order the 113th Meeting of the Blood Products Advisory Committee (BPAC). The topic of this partially closed meeting addressed the March 22, 2016 site visit report of the intramural research programs of the Laboratory of Plasma Derivatives (LPD), in the Division of Hematology Research and Review (DHRR), Office of Blood Research and Review (OBRR), Center for Biologics Evaluation and Research (CBER).

The meeting was held at the Food and Drug Administration (FDA), White Oak Campus, 10993 New Hampshire Avenue, Building 31, Silver Spring, MD 20993. BPAC members participated via teleconference for the open and closed sessions and watched the publicly available live webcast during the open session. The public was also welcome to attend the open session of the meeting at the FDA headquarters.

After the meeting was called to order by the Dr. Leitman, the Designated Federal Officer (DFO) took a roll call of the BPAC members for the public record and made administrative remarks following which the FDA staff introduced themselves. The conflict of interest statement was read by the DFO for the public record noting that the meeting topic was determined to be a non-particular matter and hence no screening of the members was done and no waivers were issued for their participation.

Open Session

During the open session, the committee heard presentations of an overview of the CBER Research and Site Visit Process from CBER's Associate Director for Research, Dr. Carolyn Wilson. An overview of OBRR's research programs was provided by Dr. CD. Atreya followed by an overview of the Division of Hematology Research and Review from its Director, Dr. Basil Golding. Following these presentations, Dr. Dorothy Scott, the Chief of the Laboratory of Plasma Derivatives, gave an overview of her research program and the progress that was made since the previous site visit. The committee was given the opportunity to ask clarifying questions following which an Open Public Hearing session was announced. However, since no public members were present and there was no public comment, the open session was adjourned at approximately 11:55 a.m. and the meeting proceeded to go to 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/BloodProductsAdvisoryCommittee/ucm501664.htm