FOOD AND DRUG ADMINISTRATION

Center for Biologics Evaluation and Research
119th Meeting of the Blood Products Advisory Committee
White Oak Conference Center
Great Room, Building 31
10903 New Hampshire Avenue
Silver Spring, MD 20993

July 19, 2018

Committee Members
Meera B. Chitlur, M.D.#
Michael DeVan, M.D., F.C.A.P.
Alfred DeMaria, M.D.
Miguel Escobar, M.D.
Robert Kaufman, M.D.
Andrei Kindzelski, M.D., Ph.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. #
Martin Schreiber, M.D., Ph.D.
Amy Shapiro, M.D. #
Jack Stapleton, M.D. #
Susan Stramer, Ph.D. #

FDA Participants
Anne Eder, M.D, Ph.D.
Peyton Hobson, Ph.D.
Julia Lathrop, Ph.D.

Guest Speakers
David Hardy, M.D.
Michele Owen, Ph.D.

Acting Chair
Angela Caliendo, MS., Ph.D., FIDSA

Consumer Representative
Judith Baker, DrPH, MHSA

Temporary Voting Members
Oluwatoyin Adeyemi, M.D.
James Allen, M.D., MPH
George Bishopric, M.D.
Jefferson Jones, M.D., MPH ##
Sheila Peel, MSPH, Ph.D., DAC

Acting Industry Representative
Brad Spring, B.S.

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

Committee Management Specialist
Joanne Lipkind, M.S.

Did not attend
Attended by phone

These summary minutes for the July 19, 2018 meeting of the Blood Products Advisory Committee were approved on _____.

I certify that I participated in the July 19, 2018 meeting of the Blood Products Advisory Committee and that these minutes accurately reflect what transpired.

//s//	//s//
_____	_____
Prabhakara Atreya, Ph.D. Director Div. Sci. Advisors and Consultants	Angela Caliendo, M.D, Ph.D Acting Chair .

For Bryan Emery, MA, BSN, LCDR
Designated Federal Official

The Acting Chair, Dr. Angela Caliendo, called the meeting of the Blood Products Advisory Committee to order at 8:00 a.m. EST on July 19, 2018. The Committee was convened as a device classification panel. The meeting was held in an open session. The Chair invited the members, temporary members and other 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, presentations began.

QUICK SUMMARY

Topic II: Device Reclassification of Human Immunodeficiency Virus (HIV) Point of Care and Laboratory-Based Serological and Nucleic Acid Diagnostic Devices

Dr. Peyton Hobson from the Division of Emerging Transfusion-Transmitted Diseases (DETTD), Office of Blood Research and Review (OBRR), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration (FDA), welcomed the committee and introduced the topic. Dr. Michele Owen from the Centers of Disease Control and Prevention (CDC) presented a historical overview and prospects for the future of HIV diagnostic devices. This presentation was followed by a presentation on the clinical application of HIV testing technology by Dr. David Hardy of Whitman-Walker Health. An overview of device classification was presented by Dr. Julia Lathrop of DETTD. After that, Dr. Anne Eder of DETTD presented the status of HIV diagnostic devices in the U.S. Dr. Julia Lathrop then presented an overview of proposed special controls. During the final presentation, there was a fire alarm that caused the building to be evacuated and g the meeting adjourned briefly.

In the interest of keeping on schedule, the committee adjourned for lunch after the presentations were completed.

After lunch, the committee reconvened for the Open Public Hearing and Dr. Angela Caliendo, the Acting Chair, read the Open Public Hearing statement. Three oral presentations were made during the Open Public Hearing.

The following individuals made comments during the Open Public Hearing:

1. Dr. Anne Gaynor on behalf of the Association of Public Health Laboratories
2. Dr. Bernard Branson
3. Dr. Shelby Smoak, Committee of Ten Thousand

Following the Open Public Hearing, the Committee discussed the following issues:

- How HIV diagnostic tests are regulated in comparison to other similar infectious disease diagnostic tests
- The stringency of the proposed performance requirements and the feasibility of clinical trials because of cost and sample availability.
- The availability of a test that has a dual intended use as a HIV diagnostic test and viral load test.
- The need for updated panel development.
- Whether the proposed special controls for HIV diagnostic tests are consistent with proposed special controls for hepatitis C virus (HCV) diagnostic tests?
- Whether real-world clinical performance reflects the performance standards in the labeling of the devices.

Dr. Peyton Hobson of DETTD presented the following question for the committee.

Discussion Question:

"Do committee members believe that the special controls as described, in addition to general controls, are sufficient to mitigate the risks to health presented by reclassification of HIV serology and NAT point-of-care and laboratory-based diagnostic and supplemental devices?"

Summary of Open Committee Discussion:

- The BPAC members unanimously supported the reclassification of HIV diagnostic tests to class II with special controls and agreed, in general, with the proposed special controls.
- Many panel members urged the FDA to also reclassify HIV viral load monitoring tests.
- Some panel members expressed concern that the performance requirements and number of samples required for clinical trials were set too high, and suggested that the FDA consider aligning the HIV requirements with those for HCV.
- Others supported the proposed performance or recommended taking an incremental approach to changing the requirements.
- Panel members commented that reclassifying the devices as Class II (special controls) will encourage new test development and also allow manufacturers s to make improvements to currently available tests.

After the Open Committee Discussion was completed, the Acting Chair, Dr. Angela Caliendo, adjourned the meeting at approximately 2:00 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/ucm554807.htm