

DRAFT - INTERNAL USE ONLY

Revised:11/30/01 1:47 PM

BLOOD PRODUCTS ADVISORY COMMITTEE
70th Meeting - December 13-14, 2001
Hilton Silver Spring Hotel
8727 Colesville Road Silver Spring, MD

Thursday, December 13, 2001

8:00 a.m. Statement of Conflict of Interest

8:05 a.m. Welcome and Opening Remarks

- Presentation of Committee Member Certificates

8:30 a.m. Committee Updates

- Current TSE Guidance - Dorothy Scott, M.D.
- Consent Decree Update - Cecily Kodis-Kaufman
- Summary of CDC Workshop on Factor VIII
- Disaster Response

10:00 a.m. BREAK

10:30 a.m. *Open Committee Discussion*

I. Potential Concerns for Simian Foamy Virus
Transmission by Blood and Blood Products

- A. Introduction and Background - Hira Nakhasi, Ph.D., Director, DETTD, OBRR, CBER, FDA
- B. Review of SFV Biology and Pathogenesis - Arifa Khan, Ph.D., OVR, CBER, FDA
- C. Review of CDC Investigation on Human Infections with SFV - Louisa Chapman, M.D., CDC
- D. Review of Health Canada Study: Risk Assessment - Paul Sandstrom, Ph.D., Health Canada
- E. FDA Proposed Animal Study on SFV Transmission by Blood - Arifa Khan, Ph.D.

12:00 NOON OPEN PUBLIC HEARING

12:30 p.m. *Open Committee Discussion*

- F. Questions for the Committee
- G. Committee Discussion and Recommendations

1:30 p.m. LUNCH

2:30 p.m. *Open Committee Discussion*

II. Discussion on Leukocyte Reduction Guidance

- A. Introduction and Background - Alan Williams, Ph.D., Director, DBA, OBRR, CBER, FDA
- B. Review of Filter Performance Data - Betsy Poindexter, DH, OBRR, CBER, FDA
- C. Establishing the Appropriate QC Cut-off for Contaminating Leukocytes
 - Edward Snyder, M.D., Yale-New Haven Hospital
 - Linda Kline, M.D., American Red Cross
- D. QC Strategy - Alan Williams, Ph.D.

3:30 p.m. BREAK

3:45 p.m. OPEN PUBLIC HEARING

Manufacturer Presentation - Baxter IMAGN
Manufacturer Presentation - Blood mixing devices

4:45 p.m. *Open Committee Discussion*

- E. Questions for the Committee - Alan Williams, Ph.D.
- F. Committee Discussion and Recommendations

5:30 p.m. RECESS (until 8:00 a.m., Friday, September 21, 2001)

Friday, December 14, 2001

8:00 a.m. *Open Committee Discussion*

III. Human Cells, Tissues and Cellular and Tissue-Based Products: Risk Factors for Semen Donation

- A. Introduction and Background - Antonio Pereira, M.D., Human Tissue Staff, OBRR, CBER, FDA
- B. Current Practices in Semen Banking - Charles Sims, M.D. Los Angeles, CA
- C. Incidence and Prevalence of HIV, HBV, HCV and Other STDs among High Risk Groups - Linda A. Valleroy, Ph.D., Division of HIV/AIDS Prevention, NCHSTP, CDC
- D. Risk of and Actual Transmission of HIV, Hepatitis, and Other STDs by Semen - Deborah Anderson, Ph.D., Brigham & Women's Hospital,
Boston, MA
- E. HHV-8 as an Emerging Pathogen - Michael Ph.D., Epidemiologist, Division of Rickettsial Diseases, CDC

Hospital,
Cannon,
Viral and

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10:15 a.m. BREAK

10:45 a.m. *Open Committee Discussion*

Retesting F. Benefits of Semen Quarantine and Donor
- George Schreiber, Ph.D., Westast

G. Cryopreservation of Semen - TBD

H. Achieving Pregnancy Using Fresh vs.
Cryopreserved Semen for Semen Insemination -

OB-GYN, Emmet J. Lamb, M.D., Professor Emeritus,
Stanford University, Stanford, CA

11:30 a.m. OPEN PUBLIC HEARING

Industry Presentations

1:00 p.m. LUNCH

2:00 p.m. *Open Committee Discussion*

I. Questions for the Committee - Antonio Periera,
M.D.

J. Committee Discussion and Recommendations

3:30 p.m. ADJOURNMENT