

Draft Agenda:09/12/03

BLOOD PRODUCTS ADVISORY COMMITTEE  
77<sup>th</sup> Meeting - September 18, 2003  
Hilton Gaithersburg, 620 Perry Parkway  
Gaithersburg, MD 20877

Thursday, September 18, 2003

8:00 a.m. Welcome, Statement of Conflict of Interest,  
Announcements

8:15 a.m. Committee Updates

- ?? Summary of PHS Blood Safety and Availability Advisory  
Committee Meeting - Lawrence McMurtry - 20'
- ?? Approval of HIV-1 Group "O" Sensitive Assays - Paul Mied,  
PhD 5'
- ?? Revised Guidance on Severe Acute Respiratory Syndrome  
(SARS) - Sharyn Orton, PhD - 5'
- ?? Current Thinking on Use of Chlorhexidine as an Arm  
Preparation for Donor Phlebotomy - Leslie Holness, MD -  
5'
- ?? Labeling and Storage: Blood and Blood Components  
(Proposed Regulation) - Elizabeth Callaghan - 5'
- ?? Overview of Counterterrorism Exercise (TOPOFF II) -  
Richard Lewis, PhD - 5'

9:00 a.m. Open Public Hearing

9:20 a.m. *Open Committee Discussion*

9:35 a.m. BREAK

10:00 a.m. *Open Committee Discussion*

- I. West Nile Virus (WNV) - Informational
  - A. Introduction and Background - Hira Nakhasi,  
PhD, Director, Division of Emerging and  
Transmitted Diseases, OBRR - 15'
  - B. Epidemiology and Surveillance -  
Anthony Marfin, MD, CDC - 15'
  - C. Plasma and Plasma Derivatives Safety - 45'
    - FDA Current Thinking - Mahmood Farsid,  
PhD, DH, OBRR - 15'
    - Presentation - PPTA -30'

11:30 a.m. OPEN PUBLIC HEARING - 60'  
Industry Presentations

12:30 NOON     *Open Committee Discussion*

                  D. Committee Discussion

1:30 p.m.     LUNCH

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

                  II. Supplemental Testing for HIV and HCV

                  A. Introduction and Background - 20'

                  - Robin Biswas, MD/Indira Hewlett, PhD,  
                  DETTD, OBRR

                  B. Performance of HIV and HCV Supplemental  
                  Assays -

                  1. Miriam Alter, PhD, CDC - 15'

                  2. Steve McDougal, MD, CDC - 15'

                  3. Michael Busch, MD, PhD, Blood  
                  Centers of the Pacific - 15'

                  4. Susan Stramer, PhD, ARC - 15'

4:00 p.m.     BREAK

4:15 p.m.     OPEN PUBLIC HEARING

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

                  C. Questions for the Committee

                  D. Committee Discussion and Recommendations

6:00 p.m.     ADJOURNMENT