

(DRAFT) AGENDA

**BLOOD PRODUCTS ADVISORY COMMITTEE**  
86th Meeting - March 9-10, 2005  
Hilton Hotel, Washington DC North / Gaithersburg  
620 Perry Parkway, Gaithersburg, MD 20877

Thursday, March 9, 2006

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

8:15 a.m. Committee Updates

- Meeting Summary of DHHS Advisory Committee on Blood Safety and Availability - Jerry Holmberg, PhD, Executive Secretary, Advisory Committee on Blood Safety and Availability (15')
- Current Considerations for blood donor screening for West Nile Virus - Pradip Akolkar, Ph.D., OBRR, FDA (15')
- Classification of Transfusion Recipient ID Systems - Sheryl Kochman, OBRR, FDA (15')
- Workshop Summary - Behavior- Based Donor Deferrals in the NAT ERA- Andrew Dayton, MD, OBRR, FDA (15')

9:15 a.m.

I. Rapid Tests for Detection of Bacterial Contamination of Platelets

A. Introduction and Background - Jaroslav Vostal, MD, PhD, OBRR, FDA (30')

9:45 a.m. OPEN PUBLIC HEARING

10:30 a.m. BREAK

11:00 a.m. OPEN PUBLIC HEARING

11:30 a.m. Open Committee Discussion

B. FDA Perspective and Questions for the Committee

C. Committee Discussion and Recommendations

12:30 p.m. LUNCH

## BLOOD PRODUCTS ADVISORY COMMITTEE

Thursday, March 9, 2005

1:30 p.m.

II. Public Comments on "Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods (DRAFT)"

A. Introduction and Review of Comments- Alan Williams, PhD, Director, Division of Blood Applications, OBRR, FDA (30')

B. Industry presentation - TBD (30')

2:30 p.m. OPEN PUBLIC HEARING

3:30 p.m. BREAK

4:00 p.m. Open Committee Discussion

C. FDA Perspective and Questions for the Committee

D. Committee Discussion and Recommendations

5:00 p.m. Adjournment

Friday, March 10, 2005

8:30 a.m.

III. Proposed Studies to Support the Approval of Over-the-Counter (OTC) Home-Use HIV Test Kits

A. Background and Proposed Studies - Elliot Cowan, PhD, OBRR, FDA (40')

B. Clinical Experience with Approved Rapid HIV Tests - Bernard Branson, M.D., CDC (20')

9:30 a.m. OPEN PUBLIC HEARING

10:30 a.m. Break

11:00 a.m. Open Committee Discussion

C. Questions for the Committee

D. Committee Discussion and Recommendations

12:00 p.m. LUNCH

## BLOOD PRODUCTS ADVISORY COMMITTEE

1:00 p.m.

- IV. Summary of the Office of Blood Research and Review Site Visit (July 22, 2005)
  - A. CBER Research Overview- Kathryn M. Carbone, M.D., ADR, IOD, CBER (10')
  - B. OBRR Research Overview- Jay Epstein, M.D., Director, OBRR (15')
  - C. Questions- 20'

1:45 p.m.

- V. Review of Research Program Site Visit of the Division of Hematology Laboratories, OBRR, CBER (Oct 6, 2005)
  - A. Overview of the Division of Hematology Research program Basil Golding, M.D., Director, DH, OBRR- 5'
    - 1. Laboratory of Biochemistry and Vascular Biology
      - Abdu Alayash, Ph.D. - 10'
      - Felice D'Agnillo, Ph.D. - 5'
      - Questions-15'
    - 2. Laboratory of Cellular Hematology
      - Jaroslav Vostal, M.D. Ph.D. - 5'
      - Jan Simak, Ph.D. - 5'
      - Questions-15'

2:45 p.m. Open Public Hearing

2:55 p.m. Break and Clear the Room

3:15 p.m. Closed Session - Discussion of the OBRR Office Site Visit Review Report and the Division of Hematology laboratory site visit report

4:15 p.m. Adjournment