

## AGENDA

**BLOOD PRODUCTS ADVISORY COMMITTEE**  
86th Meeting - March 9-10, 2006  
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 - Linda Weir, 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. Committee Update

- Current Considerations on Implementation of New Recommendations for Donor Eligibility - Alan Williams, PhD, Director, Division of Blood Applications, OBRR, FDA (5')

1:35 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; Jaroslav Vostal, MD, PhD, OBRR, FDA (45')

B. Potential Impacts on Availability of the Draft Plateletpheresis Guidance on Collection Facilities - Louis M. Katz, MD, Executive Vice President, Medical Affairs, Mississippi Valley Regional Blood Center (30')

2:50 p.m. OPEN PUBLIC HEARING

3:45 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

## BLOOD PRODUCTS ADVISORY COMMITTEE

Friday, March 10, 2005

11:00 a.m. Open Committee Discussion

C. Questions for the Committee

D. Committee Discussion and Recommendations

12:00 p.m. LUNCH

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. - 5'

Ewa Marszal, Ph.D. - 5'

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

**BLOOD PRODUCTS ADVISORY COMMITTEE**

Friday, March 10, 2005

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