

Revised Draft #3:12/10/2002

BLOOD PRODUCTS ADVISORY COMMITTEE  
75th Meeting - December 12, 2002  
Gaithersburg Holiday Inn  
2 Montgomery Village Avenue  
Gaithersburg, MD 20877

Thursday, December 12, 2002

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

8:10 am. Committee Updates

?? Summary of Workshop on West Nile Virus, November 4-5, 2002  
- Hira Nakhasi, Ph.D.

?? Medical Device User Fees (MDUFMA) - Mary Elizabeth Jacobs,  
Ph.D.

?? Approval of the OraQuick Rapid HIV-1 Antibody Test -  
Elliot Cowan, Ph.D.

9:10 a.m. *Open Committee Discussion*

I. Bacterial Contamination

A. Background and Introduction - Alan  
Williams, Ph.D., Director, Division of  
Blood Applications, OBRR

B. Skin Preparation of Phlebotomy - John Lee,  
M.D., Chief, Blood and Plasma Branch,  
DBA, OBRR

C. Update on the Diversion Pouch - Jaro  
Vostal, M.D., Ph.D., Chief, Laboratory of  
Cellular Hematology, DH, OBRR

10:00 a.m. BREAK

10:15 a.m. *Open Committee Discussion*

D. Quality Control Approaches for Detection  
of Bacterial Contamination - Alan  
Williams, Ph.D.

E. Data Presentation - James Aubuchon, M.D.

F. Data Presentation - Tracey Manlove, MT,  
Terumo Corporation

G. Design of Clinical Trials for Clearance of  
Devices Intended for Screening of  
Platelet Products Prior to Transfusion:  
Background - Steven Wagner, Ph.D.,  
American Red Cross, Holland Lab.

H. Data Presentation - James Aubuchon, M.D.

I. Proposed Study Design - Jaro Vostal, M.D.,  
Ph.D.

12:30 p.m. OPEN PUBLIC HEARING

1:00 p.m. *Open Committee Discussion*

J. Questions for the Committee  
K. Committee Discussion and Recommendations

1:45 p.m. LUNCH

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

II. Human Parvovirus B19 NAT Testing for Whole Blood  
and Source Plasma

A. Introduction and Background - Mei-ying W.Yu  
Ph.D., Laboratory of Plasma Derivatives,

DH

B. Overview of Parvovirus B19 Infection -  
Brown, MD, Hematology Branch, NHLBI

Kevin

C. Industry Data Presentations

?? American Red Cross - Susan Stramer,  
Ph.D.

?? National Genetics Institute - Andrew  
Conrad, Ph.D.

?? Fractionators/PPTA

1. Barbee Whitaker, Ph.D.

2. Steve Petteway, Ph.D.

3. Edward Gomperts, M.D.

4:15 p.m. BREAK

4:30 p.m. OPEN PUBLIC HEARING

5:15 p.m. *Open Committee Discussion*

D. FDA Perspectives and Questions for the  
Committee - Mei-ying W.Yu, Ph.D.

E. Committee Discussion and Recommendations

6:30 p.m. ADJOURNMENT