

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. Experience with Plastic Tubing and Universal Bacterial Culturing - 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. 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 - Kevin

Brown, MD, Hematology Branch, NHLBI

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