

6/17/2003

BLOOD PRODUCTS ADVISORY COMMITTEE
76th Meeting - June 19-20, 2003
Hilton Gaithersburg, 620 Perry Parkway
Gaithersburg, MD 20877

Thursday, June 19, 2003

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

8:05 a.m. Committee Updates

?? Medical Device User Fee and Modernization Act (MDUFMA) - Mary
Elizabeth Jacobs, PhD - 5'

?? White Particulate Matter in Blood Bags - Sharyn Orton, PhD-
15'

?? Safety Reporting Requirements for Human Drug and Biological
Products - Richard Lewis, PhD 5'

?? Bovine Spongiform Encephalopathy (BSE) in Canada - Pedro
Piccardo, MD -10'

- Baxter Labs. Presentation -15'

9:05 a.m. *Open Committee Discussion*

I. Severe Acute Respiratory Syndrome (SARS) -
Informational

A. Introduction and Background - Alan
Williams, PhD, Director, Division of Blood
Applications, OBRR -15'

B. Epidemiology and Pathogenesis - Mark
Denison, MD, Vanderbilt University -15'

C. SARS: Canadian studies (epidemiology and
virology) - Anton Andonov, MD, Canadian
Science Center for Human and Animal
Microbiology, Health Canada - 15'

10:15 a.m. BREAK

10:45 a.m. D. FDA Current Thinking - Alan Williams, PhD -
20'

11:05 a.m. OPEN PUBLIC HEARING

11:45 a.m. *Open Committee Discussion*

E. Committee Discussion

12:30 p.m. LUNCH

1:30 p.m. *Open Committee Discussion*

II. West Nile Virus (WNV) - Informational

A. Introduction - Hira Nakhasi, PhD,
Director, Division of Emerging and
Transfusion Transmitted Diseases -
5'

B. Epidemiology and Surveillance Update -
Disease Anthony Marfin, MD, Centers for
Control and Prevention - 15'

C. Status of WNV test, Lot release and
validation panel development - Indira
Hewlett, PhD, Chief, Laboratory of
Molecular Virology, DETTD, OBRR
- 15'

D. Revised WNV Guidance - Sharyn Orton, PhD,
Blood Consumer Safety Officer, Division of
Applications - 15'

2:30 p.m. OPEN PUBLIC HEARING

Presentations from manufacturers -6' each

3:30 p.m. *Open Committee Discussion*

E. Committee Discussion

4:30 p.m. RECESS (until 8:30 a.m. Friday, June 20, 2003)

Friday, June 20, 2003

8:30 a.m. *Open Committee Discussion*

III. Discussion on Recovered Plasma

A. Introduction and Background - Elizabeth
Director, Callaghan, MS, SBB (ASCP), Deputy
Applications, OBRR - 10'
Division of Blood

B. Presentation - Robert Lunsford, Plasma
Resource Director, ZLB (PPTA) - 25'

C. Presentation - Kay Gregory, AABB - 25'

9:30 a.m. OPEN PUBLIC HEARING

10:30 a.m. BREAK

11:00 a.m. *Open Committee Discussion*

D. FDA Current Thinking and Questions for the
Committee - Elizabeth Callaghan - 10'

E. Committee Discussion and Recommendations

12:00 NOON LUNCH

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

IV. Vaccinia Immune Globulin Intravenous (VIGIV):
Current Thinking and Indications for Use -
Informational- 30'

A. Presentation - Dorothy Scott, MD

2:00 p.m. OPEN PUBLIC HEARING

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

3:00 p.m. ADJOURNMENT